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Confirmation

It is hereby confirmed that the attached documents are corresponding with the original pages of the international application, as identified on the following pages, filed under Article 10 of the Patent Cooperation Treaty (PCT) at the receiving office named below.

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147-13.WO-2

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PCT REQUEST

Original (for SUBMISSION)

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0-5	Petition The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
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0-7	Applicant's or agent's file reference	147-13.WO-2
I	Title of Invention	A SYSTEM FOR PERFORMING PERITONEAL DIALYSIS
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V	DESIGNATIONS		
V-1	The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.		
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VII-1	International Searching Authority Chosen	European Patent Office (EPO) (ISA/EP)	
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VIII-1	Declaration as to the identity of the inventor	-	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	-	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
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IX-1	Request (including declaration sheets)	4	-
IX-2	Description	16 15*	-
IX-3	Claims	9	-
IX-4	Abstract	1	-
IX-5	Drawings	32* 36	✓
IX-7	TOTAL	62* 65*	-


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	Accompanying Items	paper document(s) attached	electronic file(s) attached
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IX-17	PCT-SAFE physical media	-	✓
IX-19	Figure of the drawings which should accompany the abstract	3	
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11-1	Date of receipt of the record copy by the International Bureau	
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A system for performing peritoneal dialysis

Field of the invention

The present invention relates to systems for performing peritoneal dialysis on a patient and more precisely to such systems which include a liquid distribution system forming a distinct element.

10

State of the art

Peritoneal dialysis systems as defined above are described in the following patent documents : EP 0 790 841 B1, EP 0 695 397 B1, EP 0 852 953 B1, EP 0 694 125 B1, EP 0 686 237 B1, EP 0 471 000 B1, EP 0 332 690 B1, EP 0 262 182 B1, EP 0 259 464 B1 and EP 1 195 171 A2.

15

Summary of the invention

An objective of the present invention is to provide an improved peritoneal dialysis system and in particular an improved liquid distribution system.

20

This objective and many others are achieved with the system as defined in claim 1 and 38.

Preferred embodiments of the invention are defined in dependent claims 2 to 37 and 40 to 46.

25

Several advantages result from the invention, in particular :

- simpler, and therefore more efficient, liquid distribution system which may include only two distinct cavities,
- possibility to use a peristaltic pump, in particular a rotatable peristaltic pump,
- 30 - possibility to use an unidirectional pump which results in a higher precision and a longer life time,
- possibility to fix the liquid distribution system and the pump together, alternatively with vibration attenuating means,
- possibility to use a flexible membrane which covers the chambers and which include valve elements,
- 35 - the membrane may be molded,
- part of a pressure sensor can be incorporated in the membrane.

5

Those and other advantages will be better understood in the detailed description of the invention exemplified here below, together with the following figures.

Short description of the figures

- 10 Figure 1 shows in a schematic way the principle of the invention
Figure 1A shows the "fill" phase
Figure 1B shows the "drain" phase
Figure 2 illustrates a first embodiment of the invention (liquid distribution system)
Figure 3 illustrates a second embodiment (disposable cartridge) including a
15 warmer chamber
Figure 4 shows the embodiment of figure 3 in a transparent view
Figure 5 shows the back side of the embodiment of figure 3 (disposable cartridge)
Figure 6 illustrates the disposable cartridge of figure 3 with the complete tubing
set
20 Figure 7 shows an embodiment with the rotative parts (rollers) integrated on the
cycler
Figure 8 shows the embodiment of figure 7 without the rollers
Figure 9 the disposable cartridge in two parts allowing to absorb pump vibrations
Figure 10 shows a cycler without the cartridge insertion slot
25 Figure 11 illustrates a disposable cartridge opened showing the peritoneal pump
Figure 12 is an upper view of an elastic molded membrane
Figure 13 is a bottom view of the membrane of figure 12
Figure 14 shows a membrane clipping system
Figure 15 shows the cycler of figure 10 in an open state
30 Figure 16 shows a cartridge loader
Figure 17 shows the cycler of figure 10, the insertion slot opened with the
cartridge
Figure 18 shows the cycler of figure 10, the insertion slot closed with the cartridge
Figure 19 shows a front view of a valve
35 Figure 20 shows a front view of a pressure sensor
Figure 21 shows a pump race
Figure 22 shows a valve actuator and a membrane clipping system

- 5 Figure 23 shows a warmer
 Figure 24 shows a warmer casing
 Figure 25 is a table showing drain profiles
 Figure 26 shows another embodiment of the invention
 Figure 27 shows another embodiment of the invention
 10 Figure 28 shows a molded frame in an upper view
 Figure 29 shows the molded frame of figure 28 in a bottom view
 Figure 30 shows the molded frame of figure 28 fixed to a liquid distribution system
 Figure 31 shows the system of figure 30 in a cross section
 Figure 32 shows a flow preventing system

15

Numerical references used in the drawings

- | | | |
|----|-----|---|
| | 1. | Pump |
| | 2. | Liquid distribution system (cartridge) |
| | 3. | Supply means (bag) |
| 20 | 4. | Patient |
| | 5. | Patient line |
| | 6. | Drain collector |
| | 7. | First hub chamber |
| | 8. | Second hub chamber |
| 25 | 9. | Liquid supply port with valve |
| | 10. | Patient port with valve |
| | 11. | Drain port with valve |
| | 12. | Roller separator |
| | 13. | Membrane |
| 30 | 14. | Membrane frame |
| | 15. | Pressure sensor cavity (patient) |
| | 16. | Patient port with valve (warmer chamber) |
| | 17. | Warmer chamber |
| | 18. | Patient port with valve (first hub chamber) |
| 35 | 19. | Warmer port |
| | 20. | Roller element |
| | 21. | Pump race |

- | | | |
|----|-----|--|
| 5 | 22. | Roller |
| | 23. | Tube connector for warming enter line |
| | 24. | Liquid supply line |
| | 25. | Drain line |
| | 26. | Pump inlet |
| 10 | 27. | Pump outlet |
| | 28. | Warmer pouch |
| | 29. | Warmer enter line |
| | 30. | Warmer exit line |
| | 31. | Membrane pressure sensor area |
| 15 | 32. | Retaining element for pressure sensor |
| | 33. | Clip cavity |
| | 34. | Actuator |
| | 35. | Clip plunger |
| | 36. | Pressure sensor cavity (first hub chamber) |
| 20 | 37. | Pump flexible tube |
| | 38. | Warmer port with valve |
| | 39. | Membrane actuator clip |
| | 40. | Membrane pressure volute |
| | 41. | Cartridge loader |
| 25 | 42. | Pump motor + coder |
| | 43. | Air sensor |
| | 44. | Pressure sensor |
| | 45. | Pump casing |
| | 46. | Cartridge loader shaft |
| 30 | 47. | Cartridge loader frame |
| | 48. | Cartridge loader linear cam |
| | 49. | Cartridge loader motor |
| | 50. | Cartridge insertion slot |
| | 51. | Cycler |
| 35 | 52. | Cartridge motor shaft |
| | 53. | Tube connector for supply line |
| | 54. | Tube connector for drain line |

- 5 55. Tube connector for warmer exit line
 56. Pump enter line
 57. Pump exit line
 58. Sensor pressure housing
 59. Sealing flange
 10 60. Clamping member
 61. Shaft retaining member
 62. Shaft
 63. Retaining lip
 64. Clamping slot
 15 65. Opening
 66. Releasing slot

20

Detailed description of the invention

25 The peritoneal dialysis system according to the invention is shown in a schematic way in figure 1. It includes a pump 1, a liquid distribution system 2 (also named cartridge) comprising a first hub chamber 7 and a second hub chamber 8. The first chamber 7 includes a pump inlet 26 connected to the pump 1 via a pump enter line 56, a liquid supply port 9 with valve connected to supply means, e.g. to bags 3, via a liquid supply line 24 and a patient port 10 with valve connected to a patient 4 via a patient line 5. The second chamber 8 includes a pump outlet 27 connected to the pump 1 via a pump exit line 57, a drain port 11 with valve connected to a drain collector 6 via a drain line 25 and a patient port 18 with valve connected to a patient 4 via a patient line 5.

35 Figure 1A shows the "fill" phase where liquid is supplied to the patient 4 from and through the following elements : Bag 3 – Liquid supply line 24 – (open) liquid

- 5 supply port 9 – First chamber 7 – Pump inlet 26 – Pump enter line 56 – Pump 1 – Pump exit line 57 – Pump outlet 27 – Second chamber 8 – (open) Patient port 18 – Patient line 5 – Patient 4.

10 Figure 1B shows the "drain" phase where liquid is drained from and through the following elements : Patient 4 – Patient line 5 – (open) Patient port 10 – First chamber 7 – Pump inlet 26 – Pump enter line 56 – Pump 1 – Pump exit line 57 – Pump outlet 27 – Second chamber 8 – (open) Drain port 11 – Drain line 25 – Drain collector 6.

- 15 The embodiment illustrated on figure 2 shows an assembly constituted by a pumping element 1 and a cartridge 2. Both elements are fixed together but may be separated. Figure 21 shows a better view of the fixation between both elements. Preferably, the pumping element 1 is fixed to the cartridge 2 by vibration attenuation means in order to minimize the vibration on cartridge 2 when
20 the pump is operating.

The upper face of the cartridge contains a first hub chamber 7 , a second distinct hub chamber 8 and a cavity 15 which forms part of a pressure sensor. The first chamber hub chamber 7 has three liquid supply ports 9, one patient port 10, one
25 pump inlet 26 and a cavity 36 which forms part of a pressure sensor. The second hub chamber 8 has a patient port 18, a drain port 11 and a pump outlet 27.

The pumping element 1 comprises a pump casing 45 which contains three rollers 22 maintained around the pump casing center by a roller separator 12. The space between the roller-roller separator element and the pump casing defines a pump
30 race 21 in which a flexible tube 37 is placed. The flexible tube being connected with the pump enter 56 and exit 57 lines. The rollers 22 may be motor driven by a shaft 52 (not shown on figure 2) in such a way as to progressively compress the flexible tube 37 resulting thereby in a peristaltic movement along the flexible tube 37.

- 35 During the "fill" phase, liquid is supplied via one tube connector 53 and liquid supply port 9 to the first hub chamber 7. It then enters the pump 1 through the

5 pump inlet 26, moves along the flexible tube 37, enters the second hub chamber 8 through the pump outlet 27 and goes to the patient 4 via patient port 18 and patient line 5.

During the "drain" phase, liquid leaves the patient 4, enters the first hub chamber 7 via patient port 10. It then enters the pump 1, moves along the flexible tube 37, enters the second hub chamber 8 and goes to the drain collector 6 via drain port 11, drain tube connector 54 and drain line 25.

It should be noted at this stage that each bag 3 may contain a specific liquid.

15 The cartridge 2 of figure 3 is identical to the cartridge of figure 2 with the exception of an additional cavity, namely a warmer chamber 17, which includes a warmer port 19 and a patient port 16. The warmer port 19 is connected to a warmer 28 (not shown on figure 3) via a warmer tube connector 55 and a warmer exit line 30. The patient port 16 is connected to the patient line 5. The second
20 hub chamber 8 contains a warmer port 38 connected to a warmer 28 (not shown on figure 3) via a warmer tube connector 23 and a warmer enter line 29.

During the "fill" phase, liquid is supplied via one tube connector 53 and liquid supply port 9 to the first hub chamber 7. It then enters the pump 1, moves along the flexible tube 37, enters the second hub chamber 8, moves into the warmer 28
25 via warmer port 38, enters the warmer chamber 17 via warmer port 19 through the tube connector 55 and goes to the patient 4 via patient port 16 and patient line 5.

As it can be seen on the embodiments of figures 2 and 3, the pump 1 is
30 unidirectional, i.e. whatever the pumping phase is, liquid in the flexible tube 37 always moves in the same direction. This feature provides several advantages. In particular a higher precision in the liquid exchange due to the same flow speed for both the fill and drain phases and a longer life time.

It is known that peristaltic pumps are usually accurate within +/- 5%. As such,
35 peristaltic pumps cannot be used for peritoneal dialysis since the volume which is filled within the patient cavity requires to be drained in the same amount within +/-

5 2%, otherwise the peritoneal cavity could be overfilled (e.g. for 12 liters
exchanged over the therapy, a 3% difference represents 360ml which is as much
as 18% of the 2 liters contained in the peritoneal cavity for each cycle) and/or the
ultra-filtration could be altered. In order to improve on the accuracy of the
exchanged volume without requiring the construction of highly accurate pumps
10 which would warranty a $\pm 2\%$ accuracy, the invention provides a method
whereby the conventional pump is used in a unidirectional way which insures the
same accuracy for both the fill and the drain phase (usually within $\pm 2\%$) and
therefore an appropriate balance of fluid. The volume filled with such a pump may
be inaccurate within $\pm 5\%$, but since the same cassette with the same flow speed
15 characteristics (namely the same flow direction) is used, the balance can be
insured within $\pm 2\%$ as required for the therapy. If the cassette would be used in
both directions, the difference in flow speed would be within $\pm 5\%$ due to the non
parallel behavior of peristaltic pumps, in particular over time.

20

It should be noted that with the present invention, the precision in the liquid
exchange is maintained even if the pump flow rate changes after a certain time
due to aging of the tubing since the fill and drain are operated within a time
window which is small in comparison to the time in which the flow speed is altered
25 by aging (e.g. a flow alteration of the pump of approximately 1% per 20 liters of
fluid pumped, with exchanged volumes of approximately 2 liters per cycle). In
addition, the use of the cassette in one direction enables a better control over the
aging of the tubing and, therefore, a better prediction of the impact on the
pumping accuracy.

30

Figure 4 is a transparent view of the cartridge which better shows how the
different elements are connected. A cartridge bottom view is shown on figure 5.
The tubing system in the lower face and the cavities of the upper face are all
made within one single part, e.g. an injected part of plastic material.

35

Figure 6 shows an assembly including the cartridge 2 of figure 3 fixed to a
pumping element 1, a patient line 5, supply bags 3, a warmer enter line 29, a

- 5 warmer outer line 30 and a warmer pouch 28 which is essentially made of a fluid circuit within a plastic bag (e.g. PVC) to be put into contact with a warming plate.

Figure 6" shows a warming plate contained into a warming system where the warming pouch has a shape of a sock to be inserted onto the warming plate. The
10 warming pouch is composed of a liquid channel which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate.

Figure 7 shows a cartridge identical to the one of figure 3 where the rollers are part of the cycler rather than of the cartridge. In this embodiment, the pumping
15 element 1 which only contains the tube and tubing race and the cartridge 2 are forming a single element.

The rollers, which are part of the cycler and therefore re-usable rather than disposable with the cardridge, have a conical shape so as to allow the rollers to be self inserted in the pump race. In this configuration the cartridge is more
20 simple to manufacture and contains less parts. No other insertion mechanism is required, since the tube is automatically compressed on the race while the rollers are penetrating into the cartridge. As a separate matter, the use of conical rollers 22 results in a more constant speed of the liquid along the flexible tube 37.

Figure 8 shows the assembly of figure 7 without the rollers 22 and the roller
25 element.

Of course, other roller shapes may be used, e.g. spherical or cylindrical.

The embodiment of figure 9 only differs from the one of figure 8 in that the pump
30 casing 45 is made out of two parts with an interface between the pumping element 1 and the cartridge 2. This configuration offers an improved assembly process of the pump and the possibility to add means to limit the propagation of the vibrations from the pump 1 to the cartridge 2.

35 Figure 10 shows a cycler 51 without cartridge 2 and pumping element 1. It contains a driving zone which includes a motor shaft 52 for the rollers 22 and several actuators 34. The cycler 51 also includes an air sensor 43 situated close

5 to the patient line 5 when the cartridge 2 is inserted. The air sensor may be made of a piezo emitter and a piezo receiver.

Figure 11 represents the embodiment of figure 2 with a flexible membrane 13 covering the hub chambers 7,8 and the pressure sensor cavity 15.

10 The upper face of the membrane 13 (see figure 12) contains several valve elements having a cylindrical cavity 39 and a pressure sensor area 31 with a ply 40 around its periphery. The valve elements 39 are designed to tightly close the ports when the membrane 13 moves downwardly.

On its bottom face (see figure 13) the membrane 13 contains a semi-circular
15 flange 32 around the pressure sensor area and annular liquid tight joints.

In addition the cartridge 2 includes liquid tight joints arranged in such a manner that they allow a liquid tight connection between the cartridge 2 and the membrane 13.

Advantageously the membrane is molded. Preferably the membrane 13 is made
20 of silicone.

The membrane 13 is press-fitted to the cartridge 2 along its periphery with a membrane frame 14 (see figure 14).

Figure 15 shows the cyclor of figure 10 in an open state which includes a pump
25 motor and a coder 42. The rectangle 41 represents the cartridge loader.

Figure 16 shows a cartridge loader comprising cartridge loader shafts 46, a cartridge loader frame 47, a cartridge loader linear cam 48 and a cartridge loader motor 49. On this figure, the two displacement parts 48' and 48'' represent two
30 different positions of the loader in an open and closed position only for explanation reasons.

The cartridge loading mechanism allows a tight connection between the membrane and the valves and the cartridge. In order to insure proper positioning of the cartridge onto the valve actuators, as well as pressure sensor and air sensor onto the right place, the cartridge is maintained into the loading
35 mechanism which progressively moves the cartridge in an axis which is perpendicular to its surface. By the same movement, the axis or the rollers can be

- 5 inserted in the right position to ensure proper functioning of the pump. The same movement can also insure appropriate pressure on the surfaces which requires to be maintained together, such as for tightness control on the membrane and/or tubing of the pump.
- 10 Figure 17 shows the cyclor 51 of figure 10 containing a cartridge 2. The cyclor 51 has an insertion slot 50 in an open position.
Figure 18 shows the same cyclor 51 but with an insertion slot in a closed position.
- 15 Figure 19 represents an actuator 34 with its plunger 35 clipped in its corresponding valve element 39 of the membrane. The actuator 34 may be a magnet or an electromagnetic element. The plunger 35 and the valve element 39 are designed to move together when the actuator is activated.
- 20 Figure 22a and 22b shows the plunger 35 and the valve element 39 in a separate position (fig. 22a) before insertion and in an activated position (fig. 22b) after insertion. One embodiment of the invention is to insure a proper insertion of the actuator head into the membrane clipping part by having the length of the part of the actuator head to be inserted into the clip of the membrane to be longer than the possible displacement of the actuator head, so as to ensure that the actuator head is always properly inserted into the clip of the membrane. As such, in the
- 25 worst case where the actuator head would be fully retracted within the actuator during the clipping translation into the membrane, the actuator head would pass the clipping equilibrium position before the end of the translation, so that the remaining translation will ensure clipping of the actuator head into the membrane.
- 30 The front view of figure 20 illustrates a pressure sensor 44 which may be used with the independent pressure sensor cavity 15 of the cartridge 2 or with the pressure sensor cavity 36 of the first hub chamber 7. The ply 40 makes the pressure sensor less sensitive to the elasticity of the membrane 13 in the sensor pressure area. In addition, the shape of the cavity 15 shall be made such that air
- 35 can be eliminated easily when fluid is passing into the cavity (e.g. by having a round shaped bottom of the cavity within the direction of the flow).

5

In the embodiments discussed previously, each port has a dedicated valve. This is not the case for the pump inlet and the pump outlet which are always kept open.

10 The invention encompasses several other features not necessarily illustrated on the figures. For instance, the cyclor or the cartridge-pumping element assembly may contain a window for detecting correct positioning of the flexible tube of the pump as shown in figure 21 (circle).

15 When the system functions, the pressure is preferably always maintained positive with respect to the drain. This is a safety measure which avoids said contaminated liquid to potentially infect the patient.

20 Advantageously the liquid pressure entering and exiting the cartridge is sensed and, if necessary, the pump flow rate is corrected in accordance with the pressure difference. This pressure difference is better calculated at the initial priming phase of the system, where the pressure is directly related to the positioning of the liquid bags 3 and the patient position relative to the cyclor.

25 Alternatively or in addition, the pump flow rate may be regulated according to a predetermined deterioration of the tubing which is known from the characteristics of the tubing.

30 The drain phase may be limited as to its duration in function of the drain speed, the drain speed having to be reduced when the patient peritoneal cavity pressure decreases, typically between 30 ml/min and 120 ml/min instead of a nominal 200 ml/min speed. This feature is particularly interesting because the dialysis efficiency is directly related to the time the liquid stays in the peritoneal cavity and the duration required to fully drain the peritoneal cavity may limit this time without a significant impact with regard to the peritoneal fluid characteristics. As such,
35 one method of the invention would be to determine at which speed it is not worth continuing draining the patient entirely and rather fill the patient with fresh fluid, taking into consideration the remaining fluid volume in the peritoneal cavity which

5 has not been expelled and expected ultra-filtration additional volume to avoid
 overfill. The cycles will therefore be all different, based on reaching a pre-
 determined drainage speed or a pre-determined decrease profile of the drainage
 speed, so that the efficient time of dialysis will be increased. An example of
 drainage speed on a patient is given in the figure 25, where, for each column
 10 which is divided in three parts, the upper part corresponding to a limit of drainage
 speed at which it is, for example, not worth continuing the drainage even if the
 next fill volume will not be a full fill. In comparison to actual method where a tidal
 at (e.g. 80%) is preset, the method under the invention is adapting each drainage
 to the actual drainage speed, trying to empty as much as possible without
 15 compromising on the efficacy of the peritoneal dialysis. Of course some limits can
 be set, where a minimum of drainage volume has to be reached before such a
 limitation takes place for each cycle.

Another method under the present invention consists to fill always as much
 20 volume, within certain limits to be set for the patient, until a certain pressure in the
 peritoneal cavity is reached. As such, the peritoneal dialysis can be improved
 since the efficiency is related to the amount of fluid filled at every cycle. According
 to such method, the pump shall fill the patient until a certain pressure is reached
 (e.g. 10cm water) and stop only once such pressure is reached or a certain
 25 maximum volume is reached. Accordingly, it is important to measure continuously
 the pressure during the dwell time to make sure that no over pressure is reached,
 such as due to the ultra-filtration. One possibility is also to always fill up to such a
 limited pressure and/or volume and drain at a certain interval thereafter a certain
 volume to compensate for expected ultra-filtration. Another possibility is to
 30 increase the ultra-filtration during the last cycle, by using e.g. low sodium
 concentrated solution.

Figure 26 illustrates another embodiment which uses peristaltic finger elements
 working on a hemispheric channel in the hard plastic part. The channel and the
 35 liquid distribution system are covered by a single membrane. A peristaltic
 pumping effect is obtained by pressing down these fingers in a sequence. This
 performs a digital type peristaltic pump with a high accuracy, which remains in

5 particular independent of inlet and outlet pressure changes. Preferably the fingers
are moved in a progressive way to simulate a peristaltic movement. Those fingers
can be operated either individually, e.g. by electric means, or by a mechanical
cam which simulates the peristaltic movement and which is rotating along the fluid
channel (e.g. a rotating disk with a variable thickness which displays a wave on its
10 surface in contact with the finger elements) . Alternatively, those fingers can be
clipped onto the membrane and be operated individually in the same manner as
the valves are, or by a rotating disk cam. In such last embodiment, the advantage
is that the position of the membrane is perfectly known in both push and pull
direction, to ensure that the peristaltic pumping is not depending on the pressure.

15

The embodiment of figure 27 only differs from the embodiment of figure 26 in that
the membrane includes cavities to receive and guide the finger elements (e.g. by
clipping means).

20 Preferably the membrane is biocompatible, allows a simple sealing to the liquid
distribution system e.g. by welding, sticking, gluing, laser or heat melting. In
addition the membrane should be made in a material avoiding the release of
particles due to mechanical stress or self migration due to the material itself (e.g.
KratonTM, SantopreneTM, BiopureTM, PebaxTM or Polyurethane). Finally the
25 membrane must be soft and elastic in order to properly perform valve and / or
pump functionalities.

It is also possible to use multi-layer material with in inner layer (on the fluid side)
which is more biocompatible and with low spallation characteristics.

30 In one particular embodiment, the membrane is also covering the fluid pumping
channel, at 45°, to ensure possible operation with either conical rollers or ball
rollers which are part of the cycler.

35 Figures 28 to 31 illustrates a molded frame which is adapted to cover in a tight
manner the space between the hub chambers, each space above said hub
chambers being covered by a flexible membrane, preferably made of injected
silicone or elastic biocompatible material. In such embodiment, the molded frame

5 and silicone or elastic biocompatible membrane can be obtained by over-molding techniques.

10 The system according to the present invention may furthermore include free flow preventing means which prevent the flow of fluid towards or from the liquid distribution system when it is released from the cycler.

15 This preventing means may be made of a mechanical clamp around the patient line, which is not clamping during the treatment will be closed automatically due to the movement of a loading mechanisms by releasing the cartridge, such as by clipping mechanism.

20 Figure 32 illustrates such a clamping mechanism which consists of a slotted clamping member 60 movably fixed to the liquid distribution system 2 via a flexible U shape member 61. Figure 32 also shows a shaft 62 which is fixed to the cycler (not shown). In the illustrated position, the liquid distribution system 2 is not fixed to the cycler. When fixation occurs, the shaft 62 is inserted through the opening 65 of the flexible U shape member 61 and retained to it by a retaining lip 63. When the liquid distribution system 2 is released from the cycler (downward movement) the bottom of the U shape member 61 is moved upwardly resulting in a movement of the clamping member 60 in the direction of the patient line 5. The patient line 5 will be kept closed as long as the shaft 62 is retained in the U shape member 61. To detach the liquid distribution system 2 completely from the cycler, the shaft 62 has to pass through a releasing slot 66.

30 Alternatively the patient line is closed by a special designed, so called "lip valve" which is normally closed. Due to a mechanical pin in the cycler the lip valve, as an integrated part of the membrane, will be open by simply pressed down with the pin coming from the cycler by mechanical movement.

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Claims

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1. A system for performing fluid administration on a patient comprising :
 - a liquid pump (1),
 - a liquid distribution system (2) connected to said pump (1) in such a way that liquid can flow from the liquid distribution system (2) to the pump (1) and vice versa,
 - liquid supply means (3) for supplying liquid to a patient (4) via said liquid distribution system (2) and said pump (1),
 - a patient conduit (5) adapted for connecting said liquid distribution system (2) to a patient (4),
 characterized by the fact that said liquid distribution system (2) comprises two distinct hub chambers (7,8), the first hub chamber (7) including at least one liquid supply port with dedicated valve means (9), one patient port with dedicated valve means (10) and one pump inlet (26) , the second hub chamber (8) including at least, one patient port (18) or warmer port (16) with dedicated valve means and one pump outlet (27), said system furthermore comprising control means arranged to close said patient port (10) of the first hub chamber (7) when said liquid supply port (9) is open and vice versa.
2. System according to claim 1 wherein said second hub chamber (8) furthermore includes at least one drain port with dedicated valve means (11), said control means being also arranged to close said patient port (18) of the second hub chamber (8) when said drain port (11) is open and vice versa.
3. A system according to claim 1 or 2 wherein said liquid distribution system (2) only includes two hub chambers (7,8).
4. A system according to anyone of the previous claims furthermore comprising a warmer system (28), a cavity (17) including a warmer port

- 5 (19) and a patient port (16), said patient port (18) of the second hub chamber (8) being connected to said warmer port (19) via said warmer system (28).
- 10 5. A system according to claim 4 wherein said warmer system (28) is a warmer in-line.
- 15 6. A system according to claim 5 wherein said warmer in-line comprises a warming plate contained therein, such warming plate being covered by a warming pouch like a sock.
- 20 7. A system according to claim 6 wherein said warming pouch is composed of a liquid channel which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate.
- 25 8. A system according to anyone of the previous claims wherein said first hub chamber (7) includes several liquid supply ports with respective valve means (9).
- 30 9. A system according to the previous claim wherein said liquid supply ports (9) are connected to respective liquid supply means having each a different kind of liquid.
10. A system according to anyone of the previous claims wherein said liquid pump is a peristaltic pump.
11. A system according to the previous claim wherein said peristaltic pump is unidirectional.
- 35 12. A system according to anyone of the previous claims wherein said liquid pump (1) is composed of a tubing and rolling surface on which the tubing is

- 5 compressed once the cartridge is inserted into a pumping device containing rollers.
- 10 13. A system according to the previous claim where said rollers (22) are of a conical shape in such a way as to be self inserted in the pump race, i.e. without any other mechanism.
14. A system according to claim 12 where said rollers are of a spherical shape.
- 15 15. A system according to anyone of previous claims 1 to 11 wherein said liquid pump (1) comprises a flexible or partially flexible channel and a series of movable finger elements successively situated above said channel, each finger element being movable along a direction which is substantially perpendicular to said channel, all finger elements being adapted to induce a peristaltic movement along said channel.
- 20
16. A system according to the previous claim wherein each finger element comprises a convex basis adapted to conform with the channel inner surface and a shaft adapted to be linked to an actuator.
- 25
17. A system according to anyone of the previous claims wherein said liquid pump (1) and said liquid distribution system (2) are fixed together to form a single cartridge.
- 30 18. A system according to the previous claim wherein said liquid pump (1) is fixed to said liquid distribution system (2) by vibration attenuation means in order to minimize the vibration on the liquid distribution system (2) when the pump is operating.
- 35 19. A system according to anyone of the previous claims wherein all hub chambers, including said ports and ports, are made within one single part.

- 5 20. A system according to the previous claim wherein said single part is an injected part of plastic material.
- 10 21. A system according to anyone of the previous claims wherein each hub chamber (7,8) is closed with an upper wall made of a flexible membrane (13), said membrane including valve elements (39) situated above each of said port or port with valve means, said valve elements (39) being designed to close said port or port when the membrane (13) moves downwardly.
- 15 22. A system according to anyone of the previous claims wherein each hub chamber (7,8) is closed with an upper wall made of a flexible membrane (13), said membrane including clipping means adapted to clip elements such as valve actuating or finger elements.
- 20 23. A system according to the previous claim wherein said membrane is molded.
- 25 24. A system according to the previous claim wherein said membrane is made out of any of the following materials: silicone, KratonTM, SantopreneTM, polyurethane, PebaxTM or BiopureTM.
25. A system according to the previous claim wherein said membrane includes liquid tight joints.
- 30 26. A system according to anyone of previous claims 21 to 25 wherein said membrane extends in such a way that it also covers said liquid pump (1).
- 35 27. A system according to claim 12, 13 or 14 wherein said liquid pump (1) comprises a flexible or partially flexible channel, said membrane covering said channel along an oblique plane, preferably at 45°, in order to allow a peristaltic movement induced by rollers or similar elements.

- 5 28. A system according to the previous claim comprising individual actuators or a cam (e.g. a disc with a vawe) adapt to induce a peristaltic movement.
- 10 29. A system according to the previous claim wherein said individual actuators are adapted to be actuated by fingers which are clipped to said membrane.
- 15 30. A system according to anyone of the previous claims wherein said liquid distribution system includes liquid tight joints arranged in such a manner that they allow a liquid tight connection between said liquid distribution system and a membrane situated on it.
- 20 31. A system according to anyone of claims 21 to 24 wherein said membrane contains protruding elements designed for a liquid tight connection between said hub chambers.
- 25 32. A system according to claim 21 wherein each of said valve elements (39) is designed to be clipped to an actuator (34), e.g. an electromagnetic actuator or a magnet, arranged above said membrane (13).
- 30 33. A system according to the previous claim wherein each of said valve elements comprises a cavity designed to receive and hold the plunger of an actuator, said cavity having an height which substantially corresponds to at least the valve displacement.
- 35 34. A system according to anyone of claim 21 to 33 wherein said membrane (13) is press-fitted along its external border to the liquid distribution system, the membrane (13) being furthermore held by a frame (14) .
- 35 35. A system according to anyone of claim 21 to 34 wherein said membrane (13) contains a portion (15) which is forming part of a pressure sensor.
36. A system according to the previous claim wherein the active area of said pressure sensor is designed to be more flexible than the remaining area.

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37.A system according to claim 35 or 36 wherein said pressure sensor has the shape of a disc of which the periphery is gripped, said disc furthermore comprising an annular ply.

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38.A system according to anyone of claims 35 to 37 wherein said pressure sensor is situated on the patient line, independently from said hub chambers.

15

39.A system according to anyone of claims 35 to 37 furthermore comprising a second pressure sensor, said second pressure sensor being in connection with the first hub chamber.

20

40.A system according to anyone of the previous claims wherein said liquid distribution system includes an air sensor situated on the patient conduit side.

25

41.A system according to anyone of the previous claims comprising a cartridge loading mechanism which allows a tight connection between the membrane and the valves and the liquid distribution system.

30

42.A system according to anyone of the previous claims comprising flow blocking means adapted to block the flow towards or from the liquid distribution system when this latter one is released out of the system.

35

43.A system according to the previous claim wherein said blocking means is a mechanical clamp situated on the patient line.

44.A system according to claim 42 wherein said blocking means is a lip valve situated on the patient line, the system furthermore comprises a movable pin adapted to open said lip valve when the liquid distribution system is released out of the system.

5

45. A system according to anyone of previous claims 21 to 44 comprising a molded frame adapted to cover the space between said hub chambers, each space above said hub chambers being covered by a flexible membrane.

10

46. A system according to the previous claim wherein said molded frame is fixed to said liquid distribution system, e.g. by ultrasound, laser welding, gluing or thermal bonding.

15

47. A system according to claim 45 or 46 wherein said molded frame is at least partially made of silicone, KratonTM, PolyurethaneTM, PebaxTM or BiopureTM.

20

48. A system according to anyone of claims 45 to 47 wherein said frame, membrane and liquid distribution system are obtained by overmolding technique.

25

49. A system according to anyone of claims 21 to 48 using a double layer membrane adapted to prevents spallation or particule release into the fluid during use .

30

50. A liquid distribution system (2) for a system performing fluid administration on a patient as defined in anyone of the previous claims.

51. A pressure sensor for a system for performing fluid administration on a patient as defined in anyone of claims 35 to 38.

35

52. A system according to anyone of the previous claims furthermore comprising a window for detecting correct positioning of the tube.

- 5 53. Method of use of the system as defined in anyone of the previous claims wherein said patient port (10) is closed when said liquid supply port (9) is open and vice versa.
- 10 54. Method according to the previous claim wherein the pressure is always maintained positive with respect to the drain.
55. Method according to claim 53 or 54 wherein said liquid is always pumped in the same direction.
- 15 56. Method according to anyone of claims 53 to 55 consisting of sensing the liquid pressure entering and exiting the liquid distribution system and, if necessary, correct the pump flow rate in accordance with the pressure difference.
- 20 57. Method according to anyone of claims 53 to 56 consisting in regulating the pump flow rate according to a known predetermined alteration of the flow rate by aging of the tubing.
- 25 58. Method according to anyone of claims 53 to 57 wherein the drain phase is a function of the drain speed, said drain phase being ended when the speed is reaching a certain value based on the patient peritoneal cavity pressure measurement.
- 30 59. Method according to anyone of claims 53 to 58 wherein the peritoneal volume filled during a cycle is a function of the intra-peritoneal pressure.
- 35 60. Method according to the previous claim wherein the peritoneal cavity is partially emptied as soon as the pressure has reached a predefined threshold.

5 61. Method according to anyone of claims 53 to 60 consisting in the use of a low Natrium concentration liquid for the last exchange cycle to improve ultra-filtration.

10 62. Use of a system as defined in anyone of the previous claims for peritoneal dialysis.

15 63. A system for performing fluid administration on a patient comprising a flexible membrane forming a valve seat characterized by the fact that said membrane includes a clipping mechanism adapted to be reversibly attached to a moving actuator in such a way that the membrane movement can be controlled in a push and a pull operation mode.

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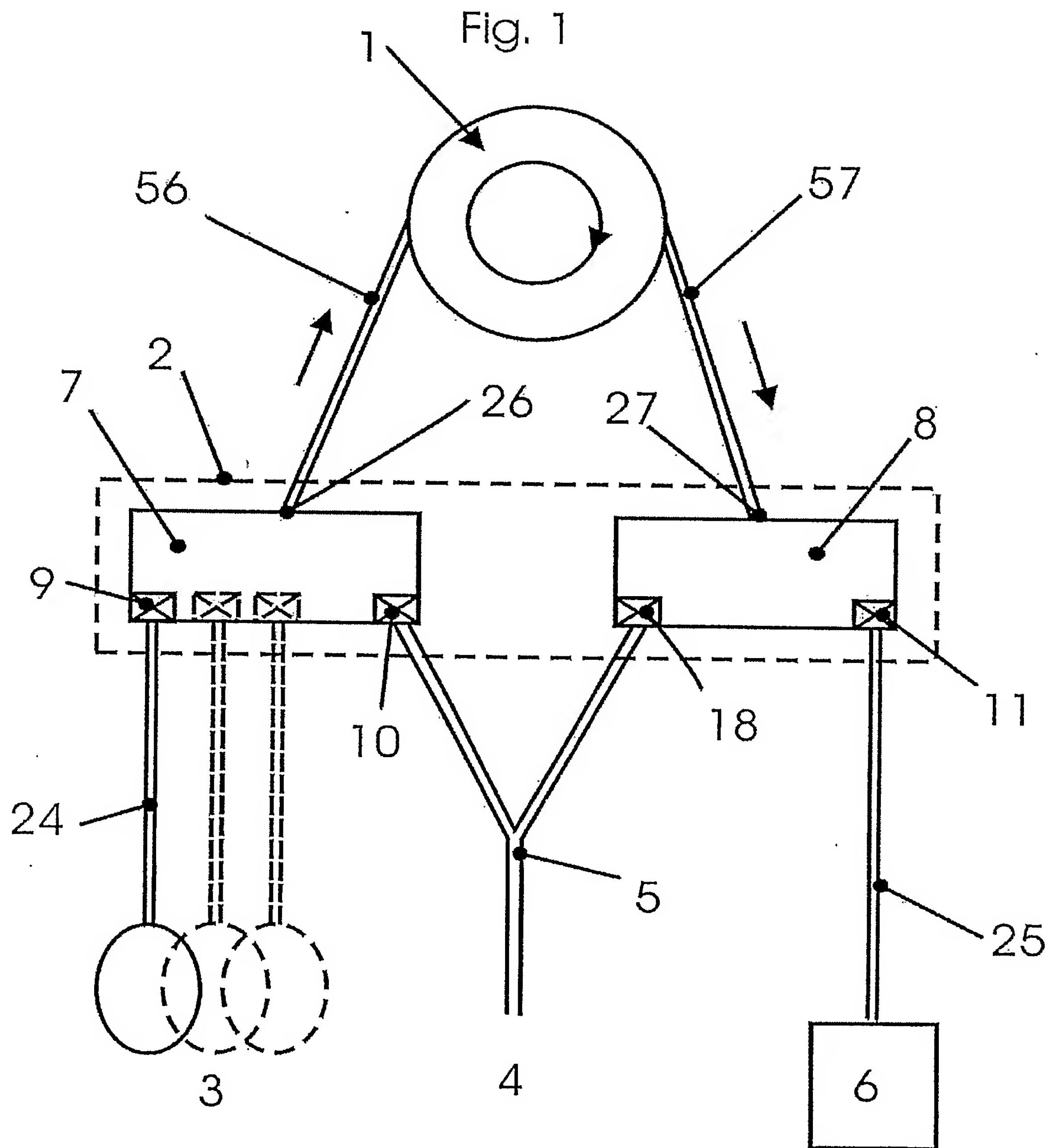
Abstract

The invention concerns a system and a method of use of said system for performing fluid administration on a patient, the system comprising :

- 10 - a liquid pump (1),
- a liquid distribution system (2) connected to said pump (1) in such a way that liquid can flow from the liquid distribution system (2) to the pump (1) and vice versa,
- liquid supply means (3) for supplying liquid to a patient (4) via said liquid
15 distribution system (2) and said pump (1),
- a patient conduit (5) adapted for connecting said liquid distribution system (2) to a patient (4),

the system being characterized by the fact that said liquid distribution system (2) comprises two distinct hub chambers (7,8), the first hub chamber (7) including at
20 least one liquid supply port with dedicated valve means (9), one patient port with dedicated valve means (10) and one pump inlet (26) , the second hub chamber (8) including at least, one patient port (18) or warmer port (16) with dedicated valve means and one pump outlet (27), said system furthermore comprising control means arranged to close said patient port (10) of the first hub chamber
25 (7) when said liquid supply port (9) is open and vice versa.

(Fig. No. 3)



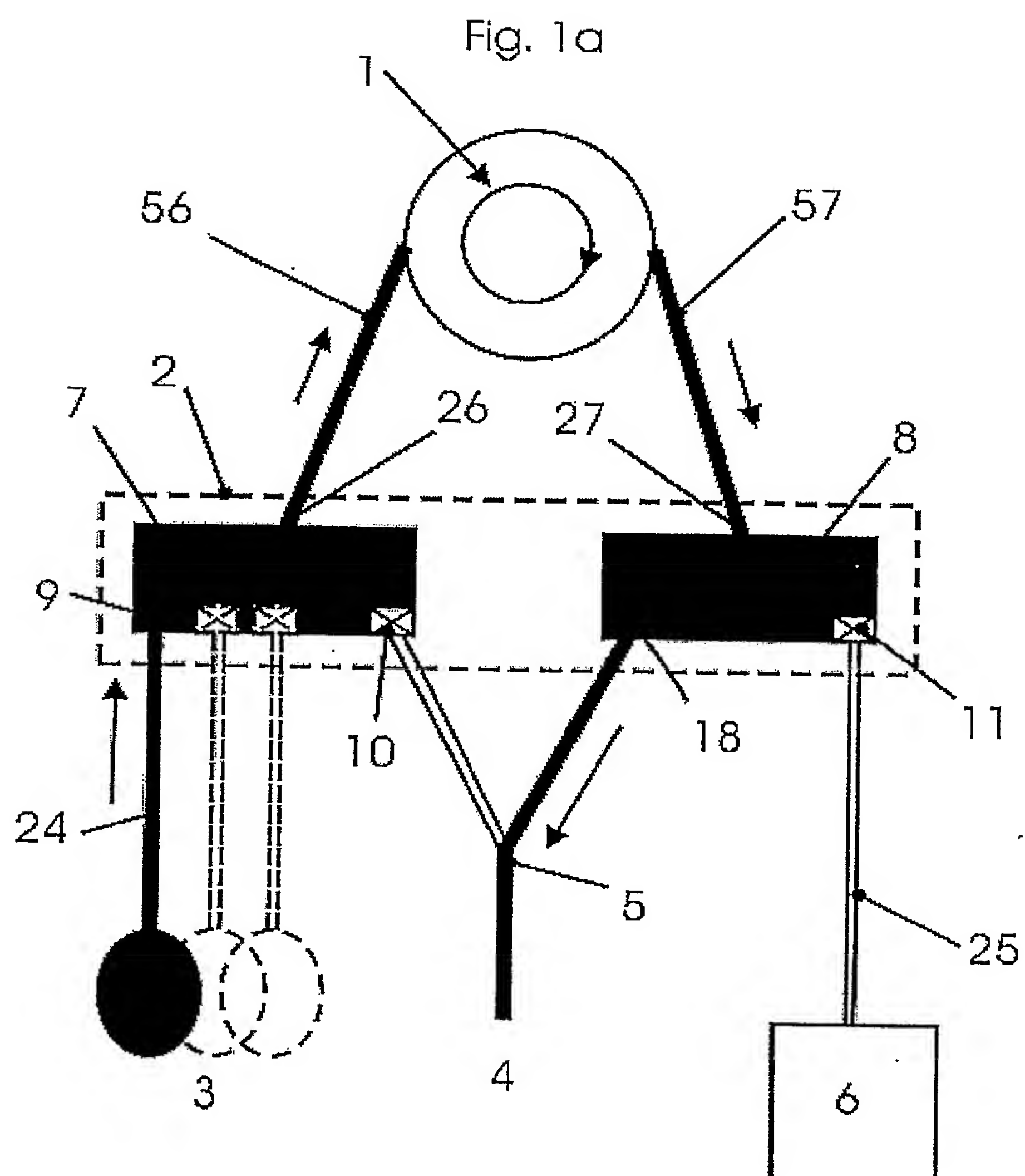
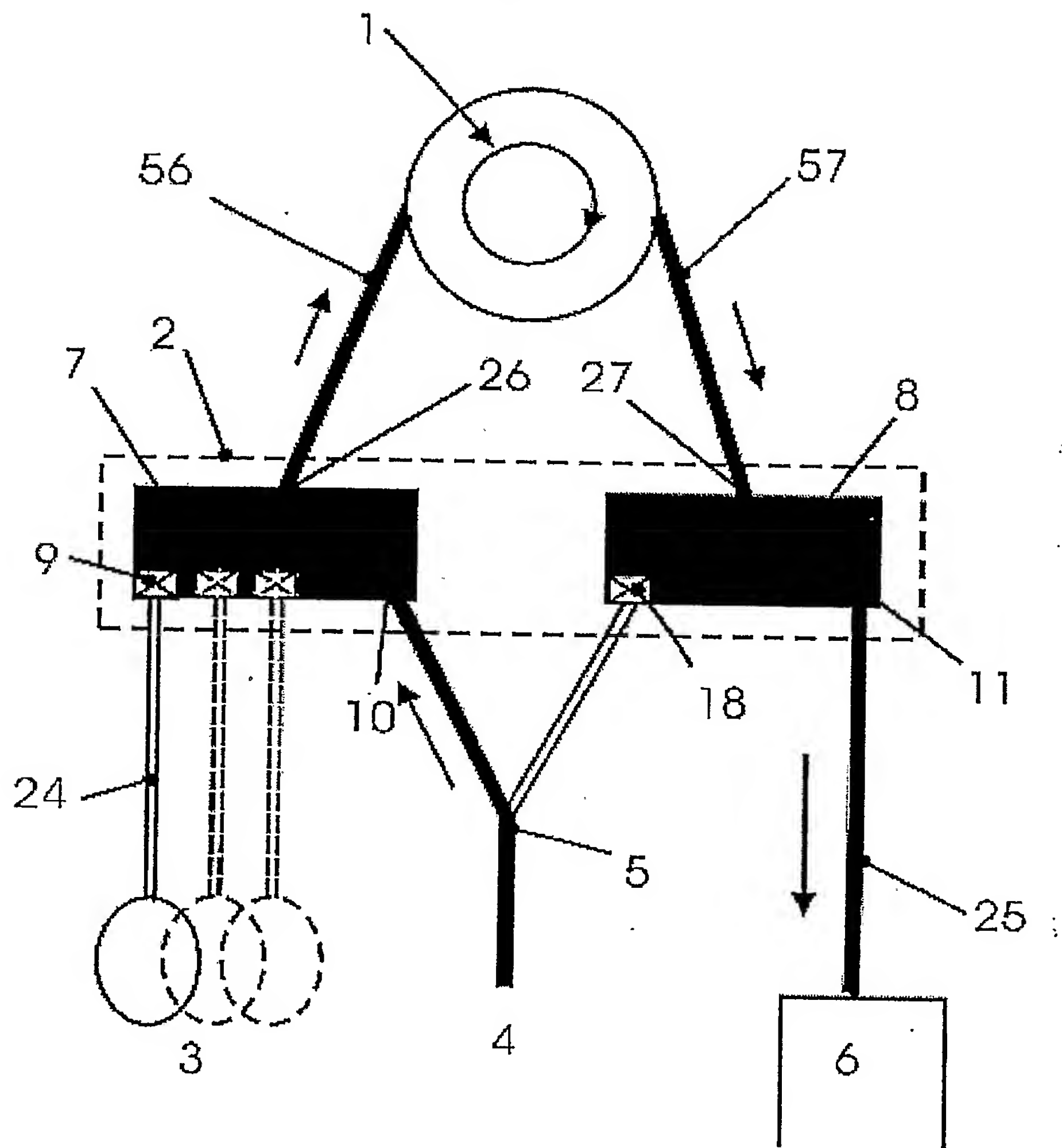


Fig. 1b



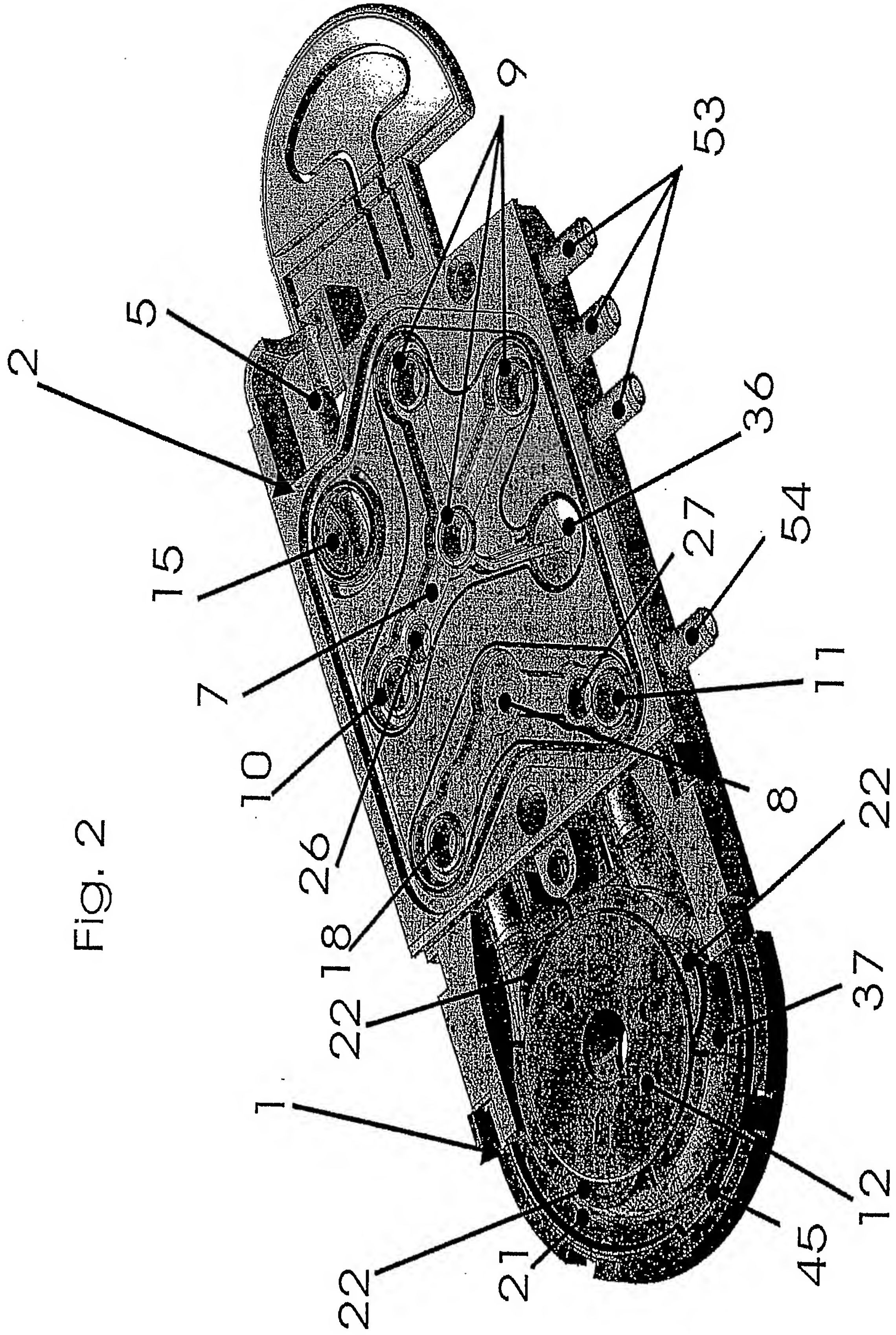


Fig. 3

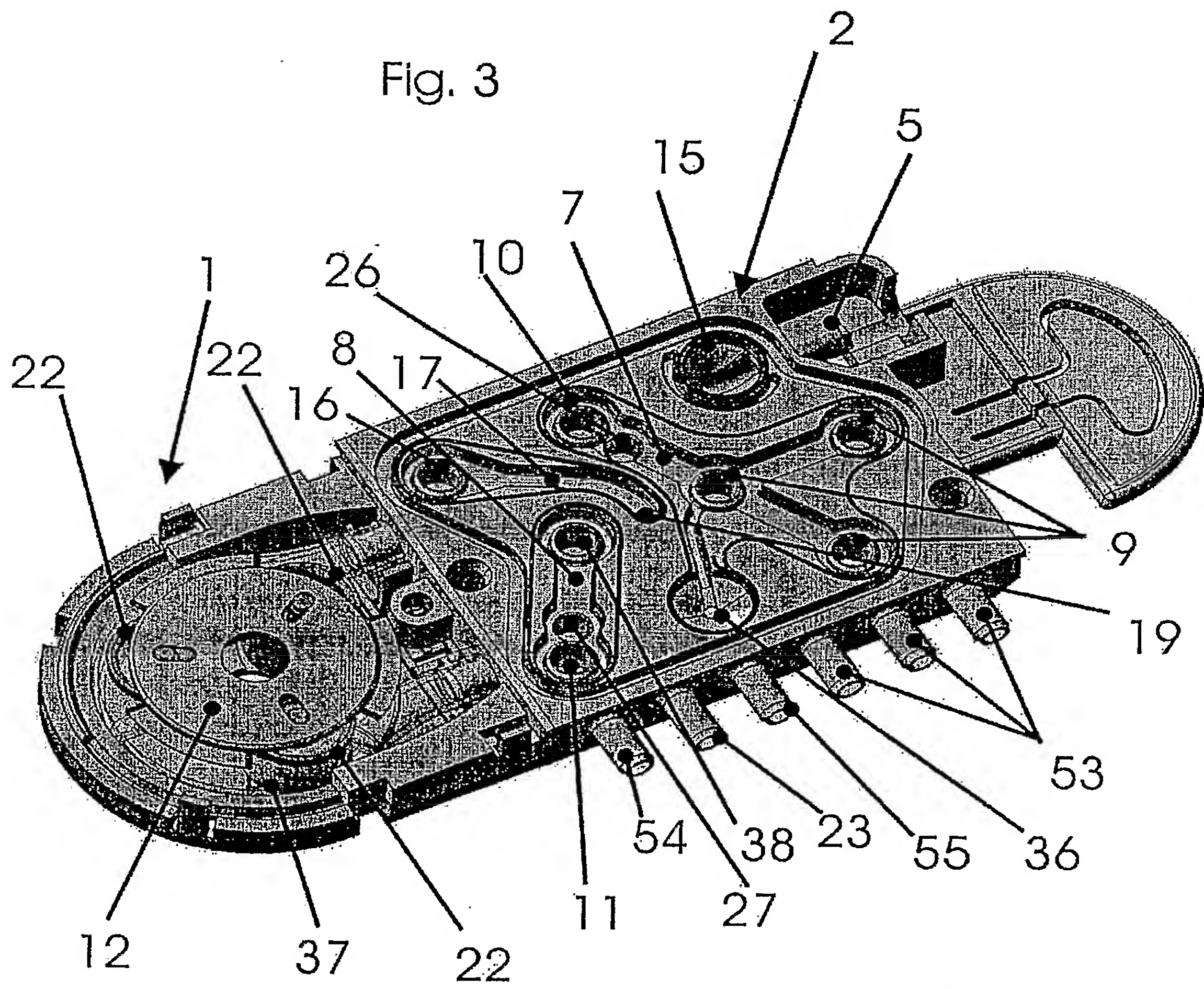


Fig. 4

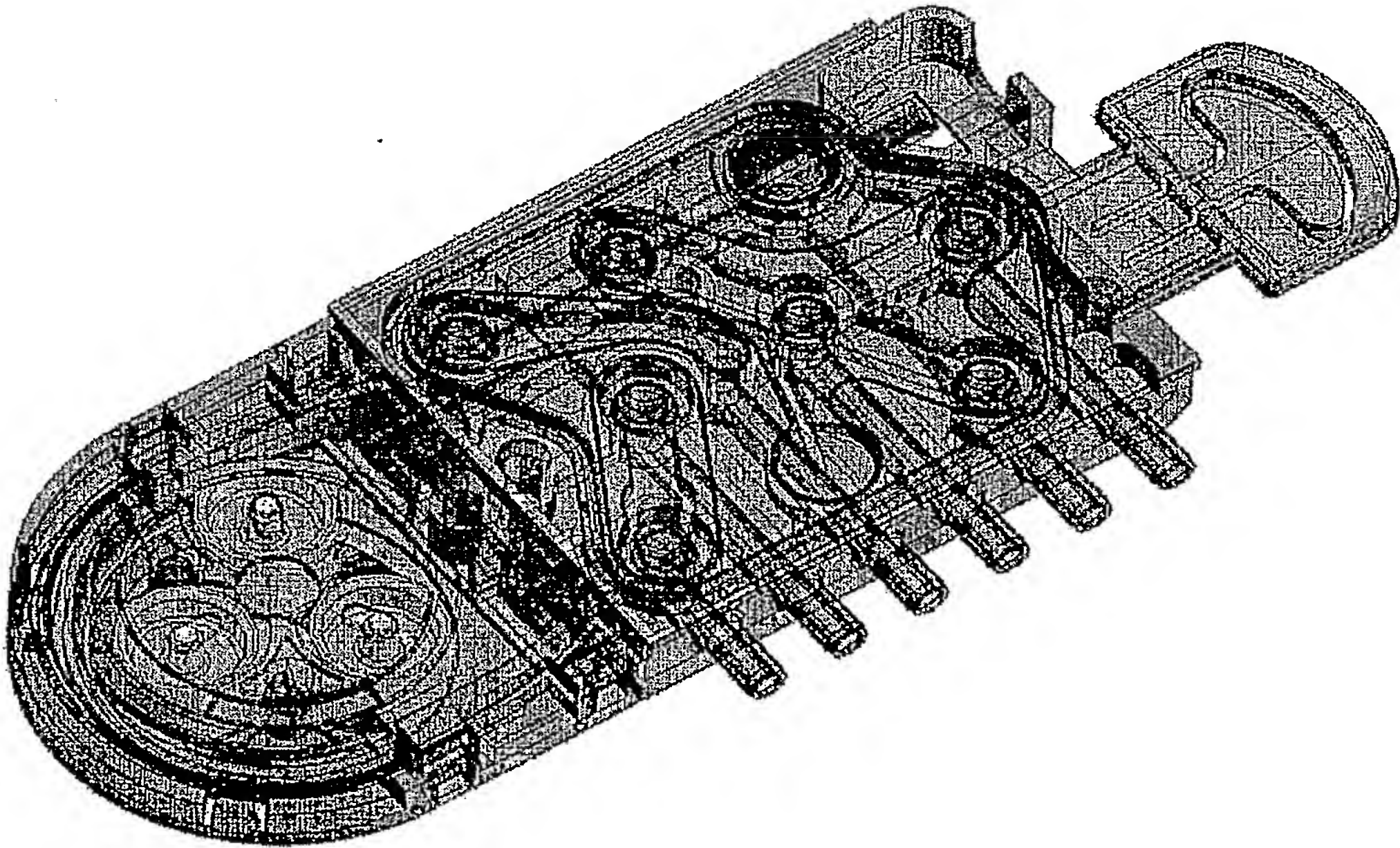


Fig. 5

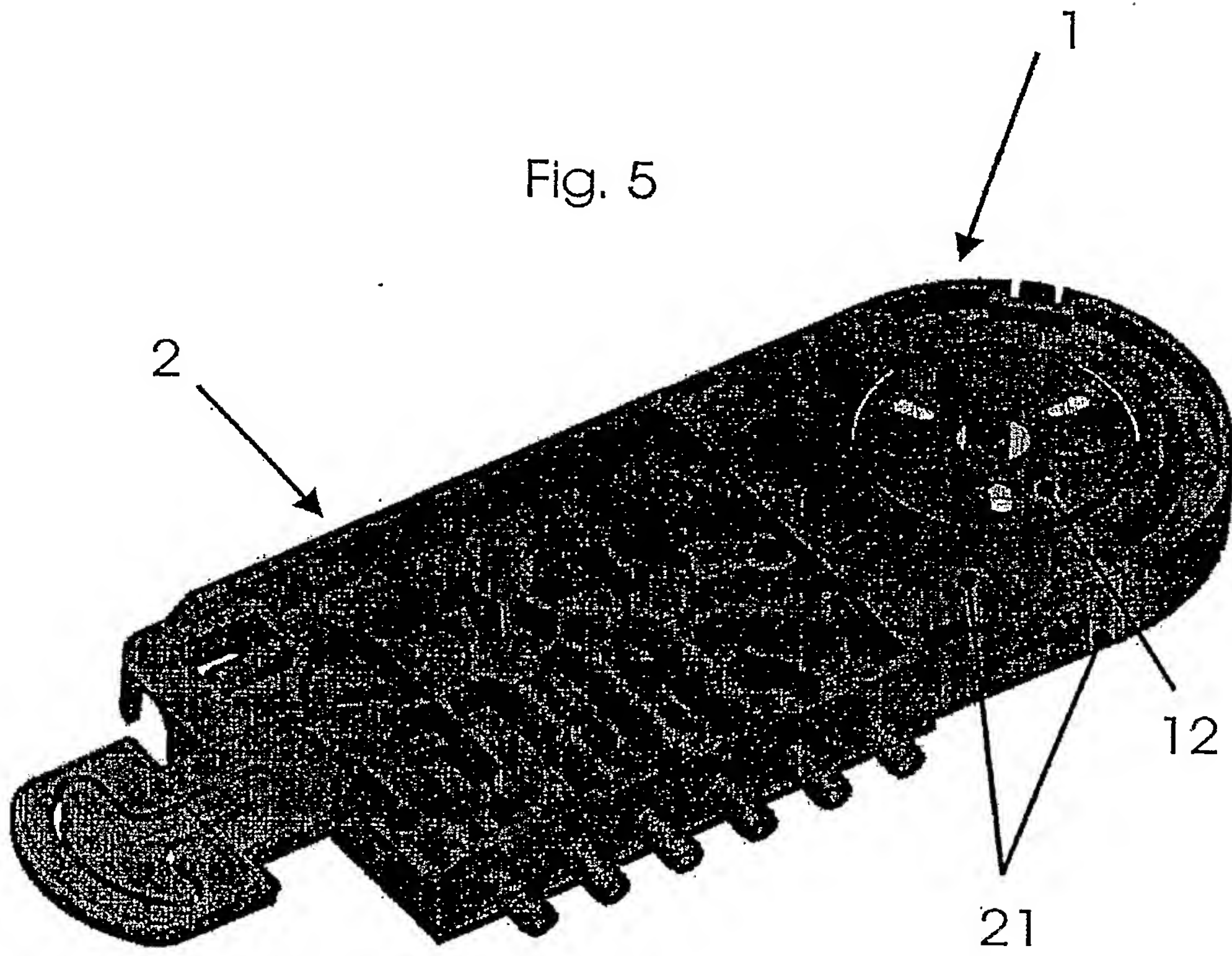


Fig. 6

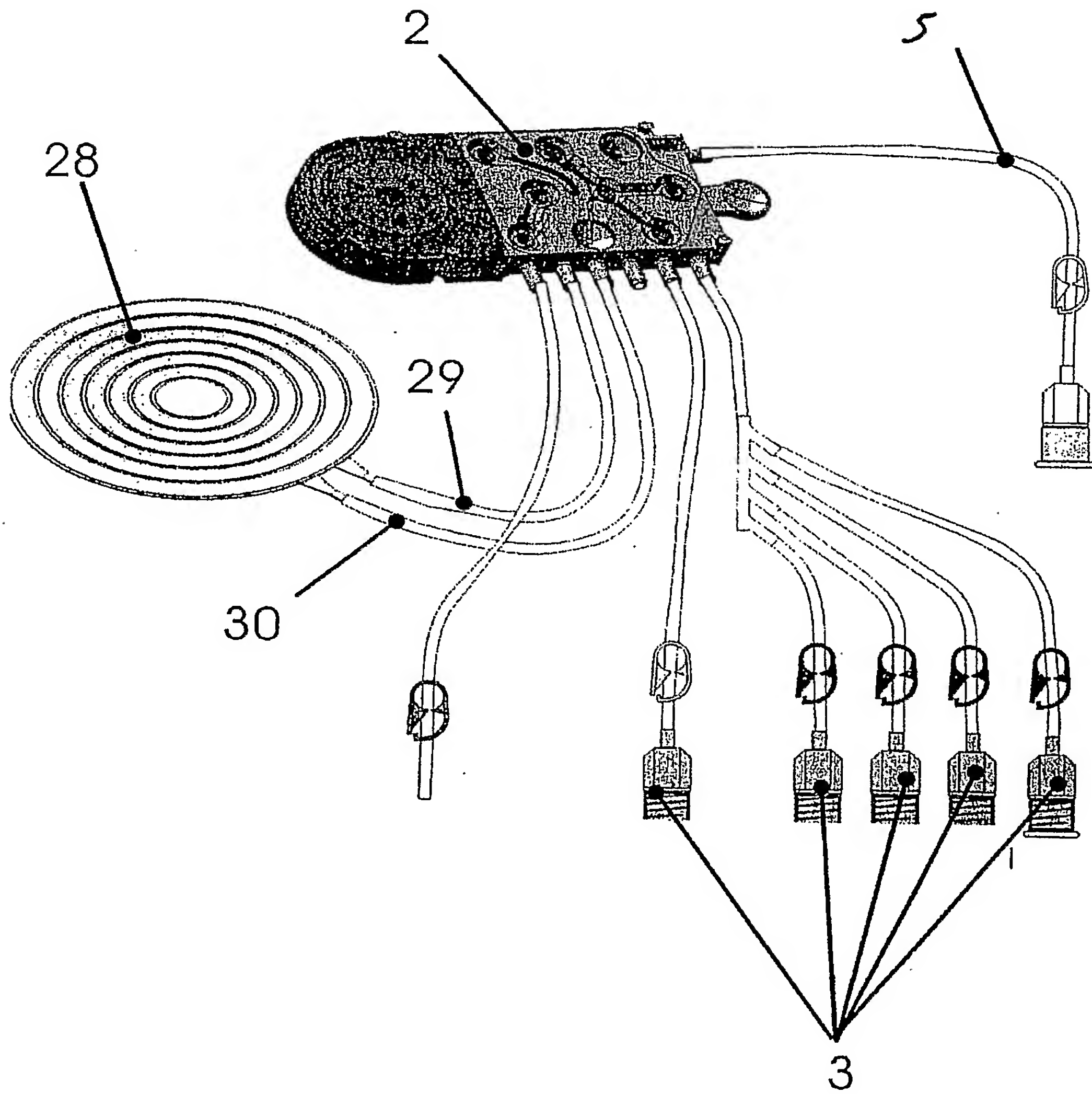


Fig. 7

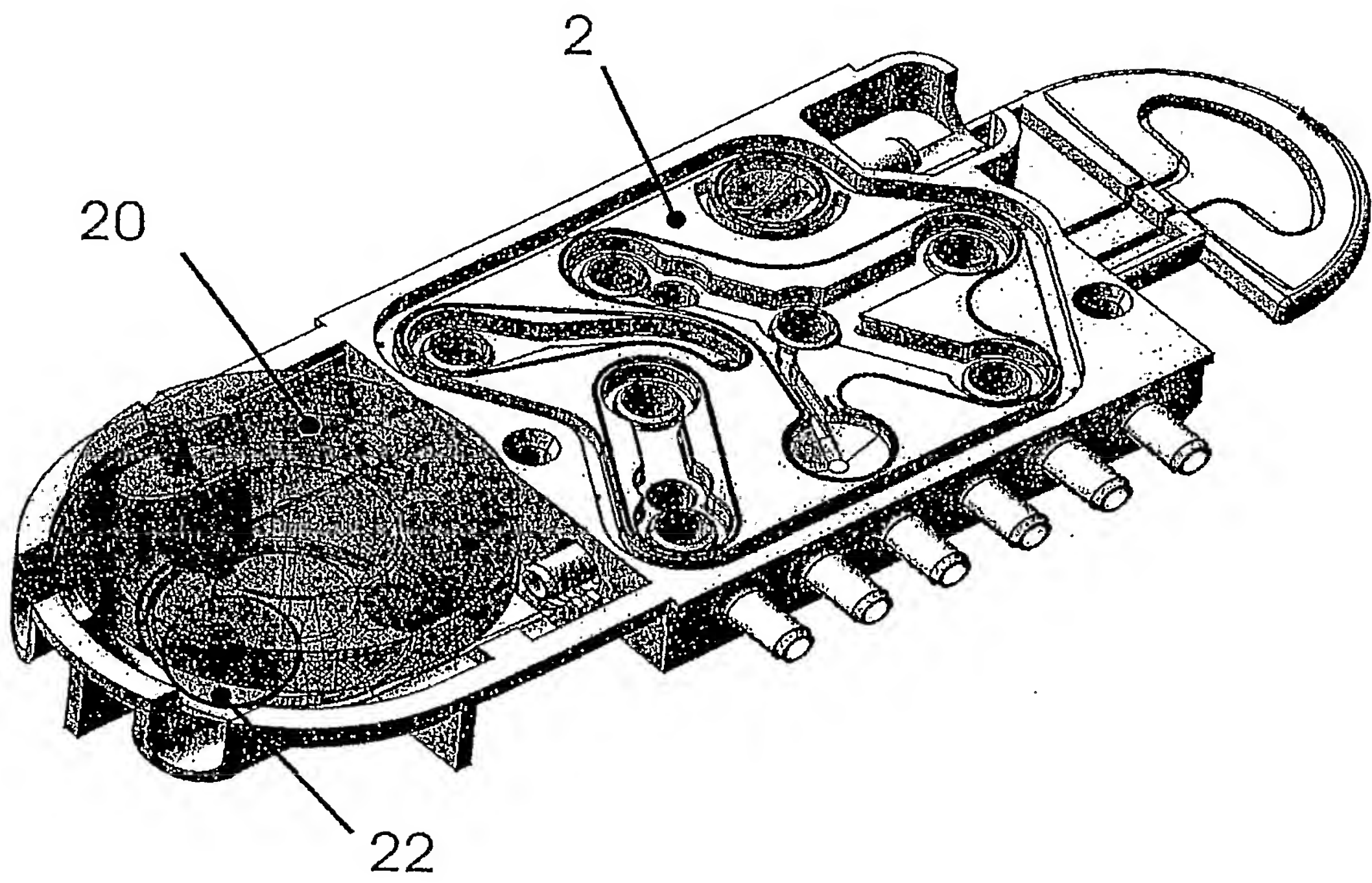


Fig. 7a

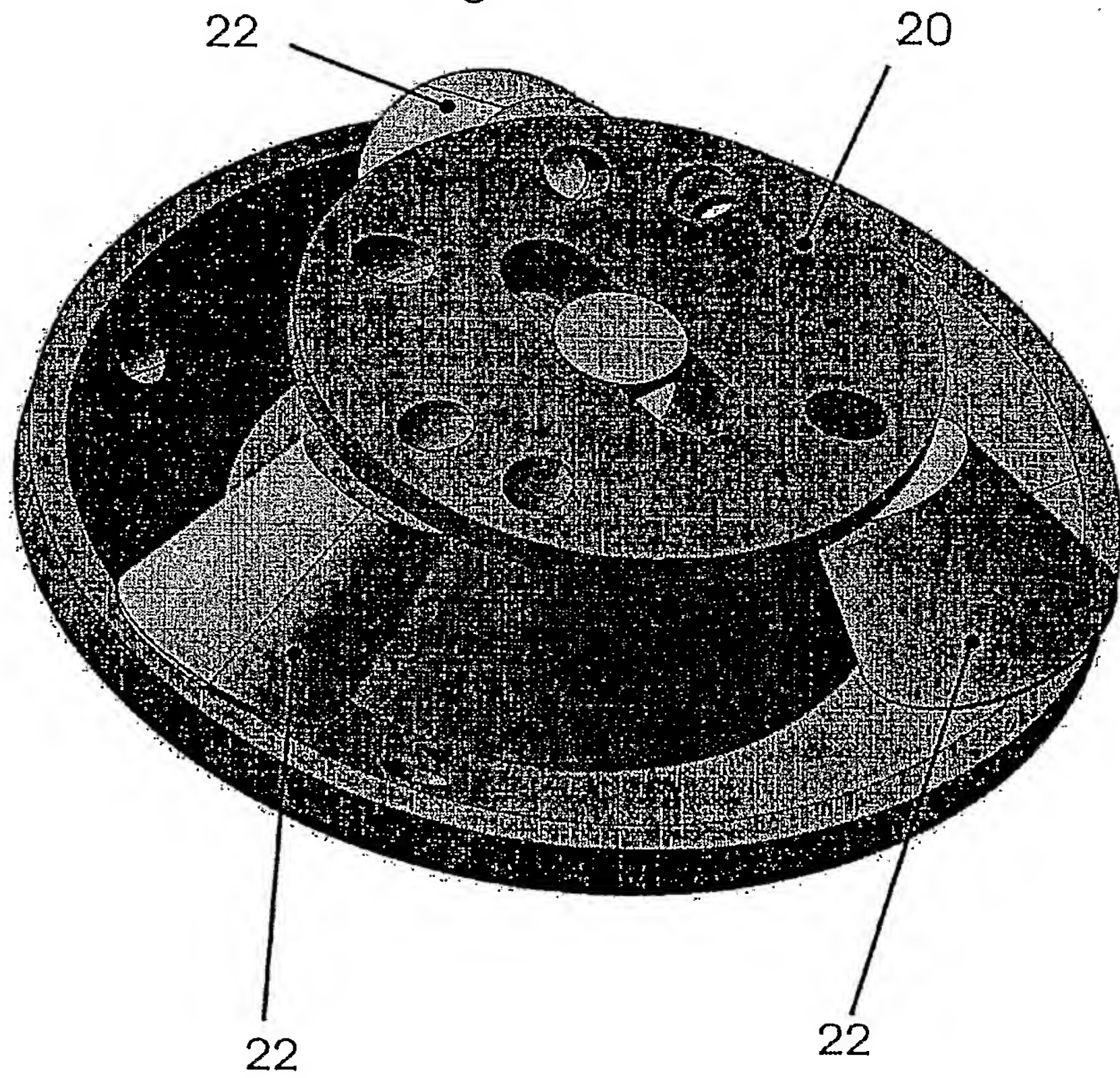


Fig. 8

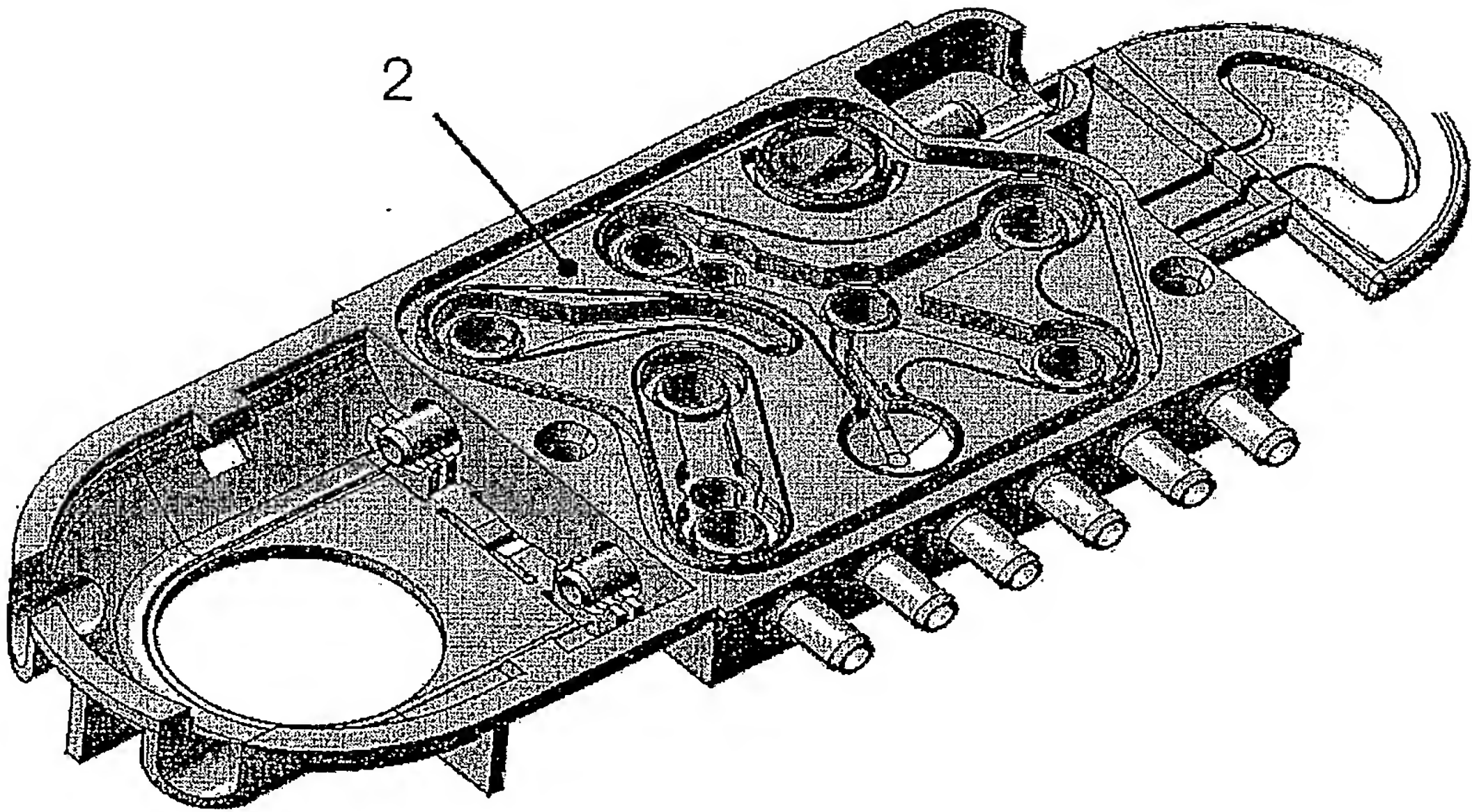


Fig. 9

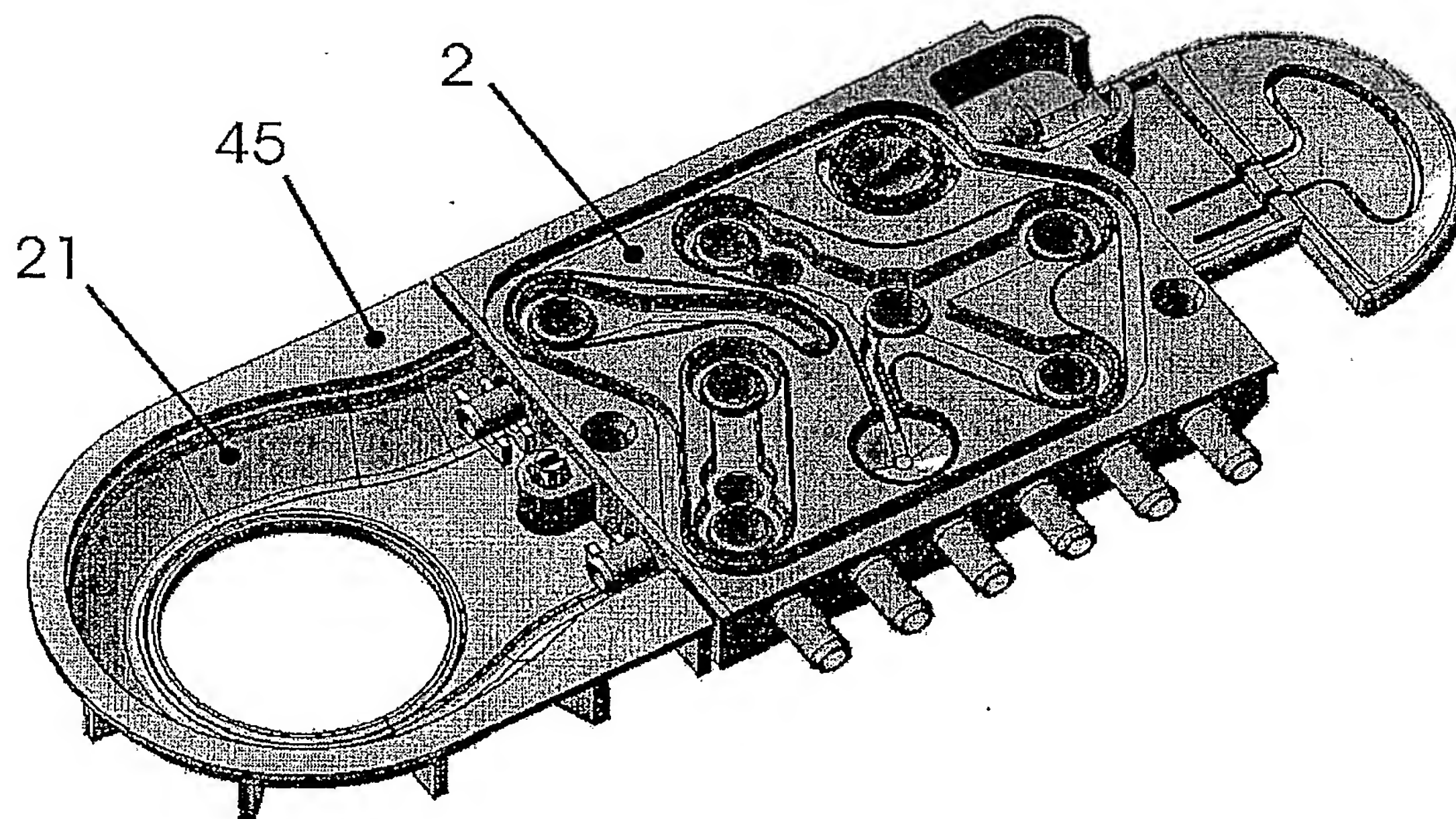


Fig. 10

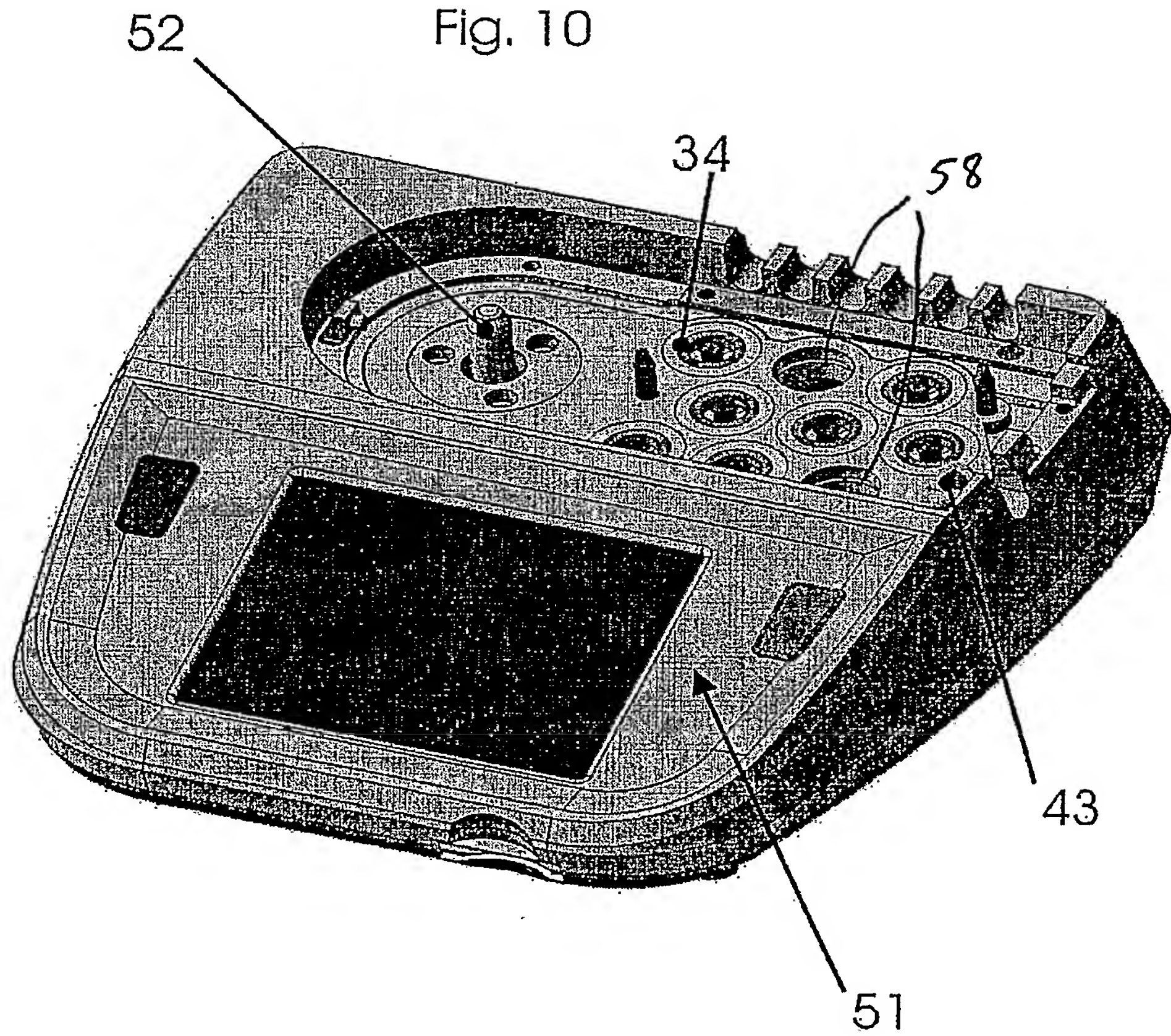


Fig. 11

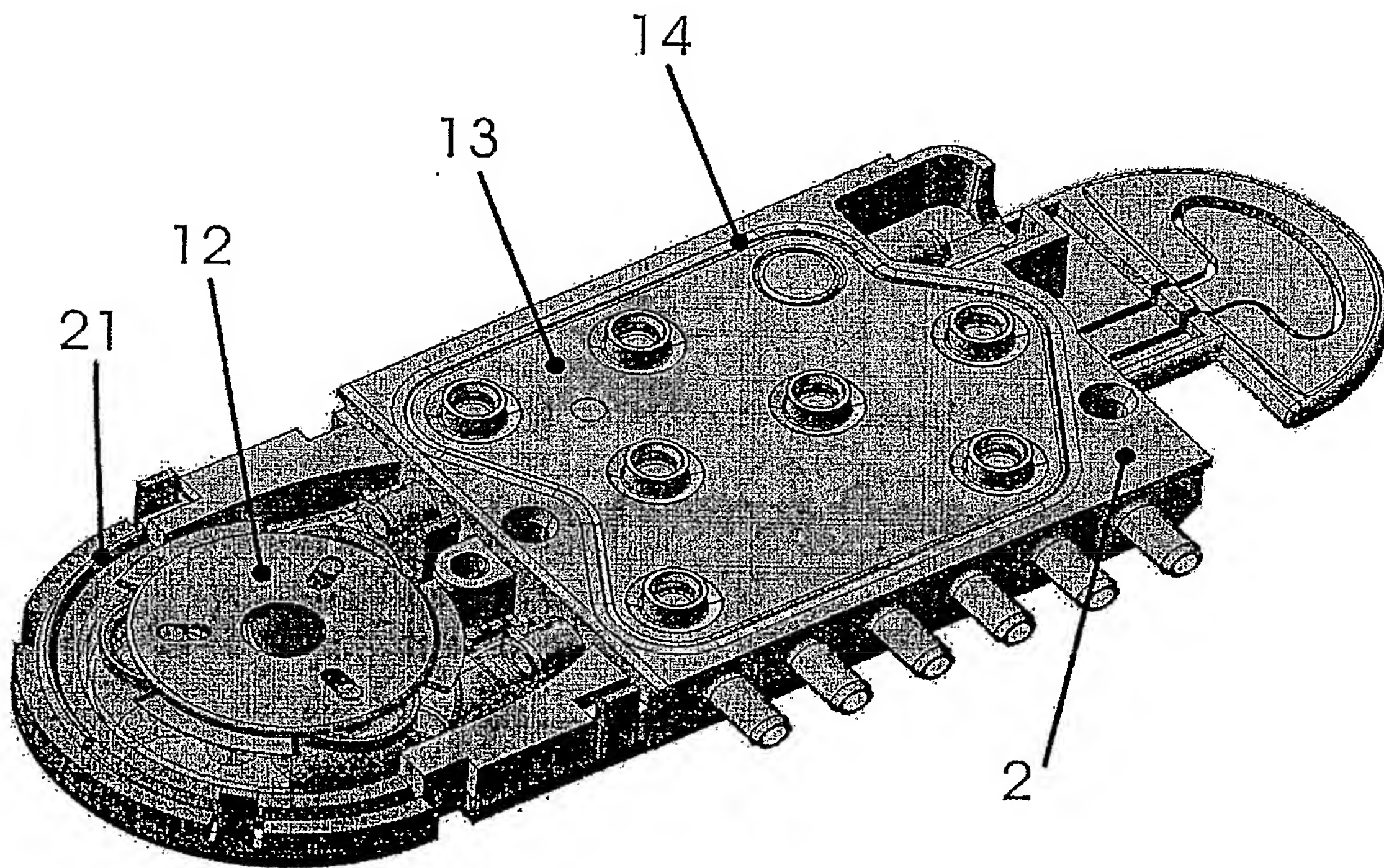
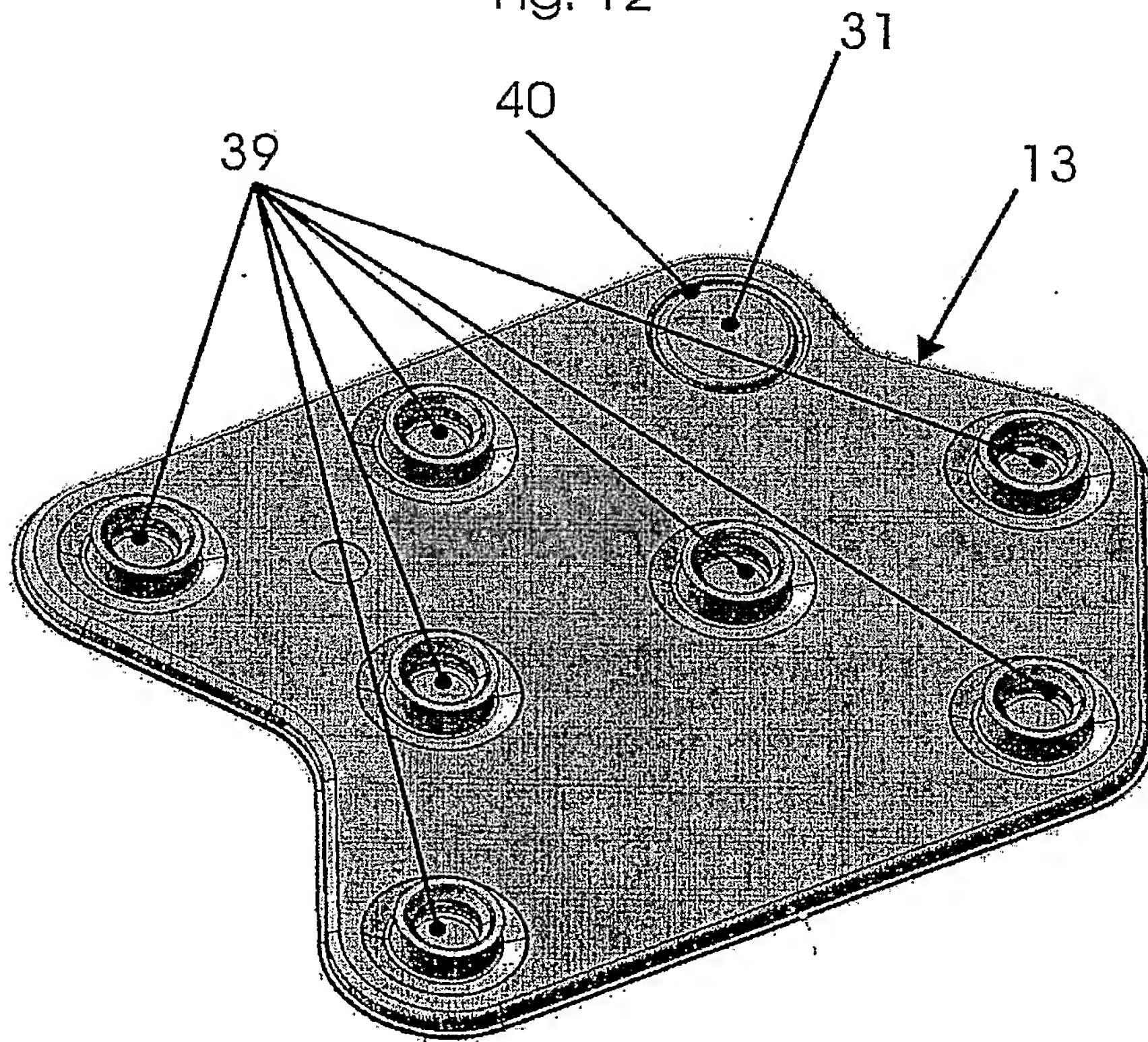


Fig. 12



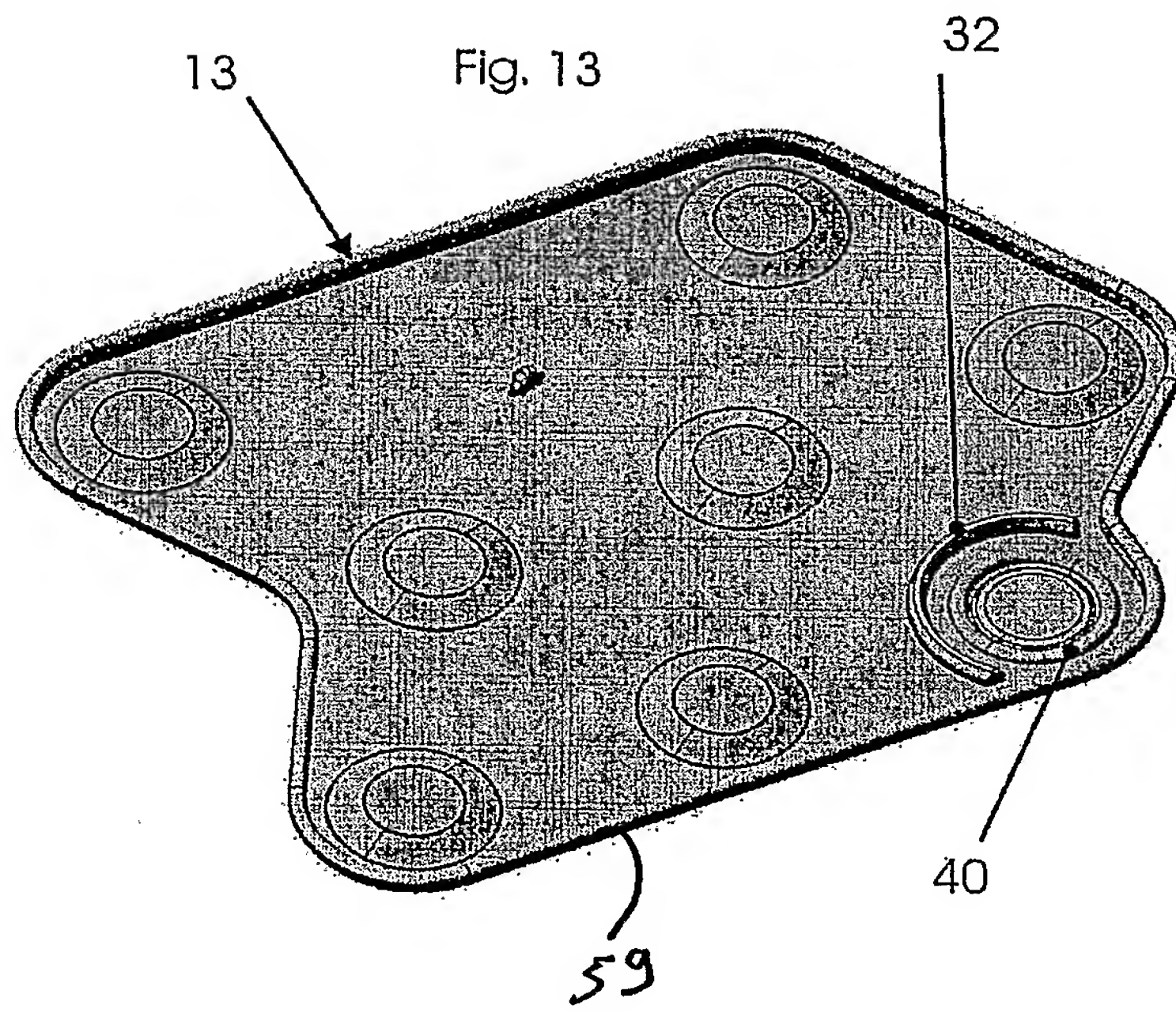


Fig. 14

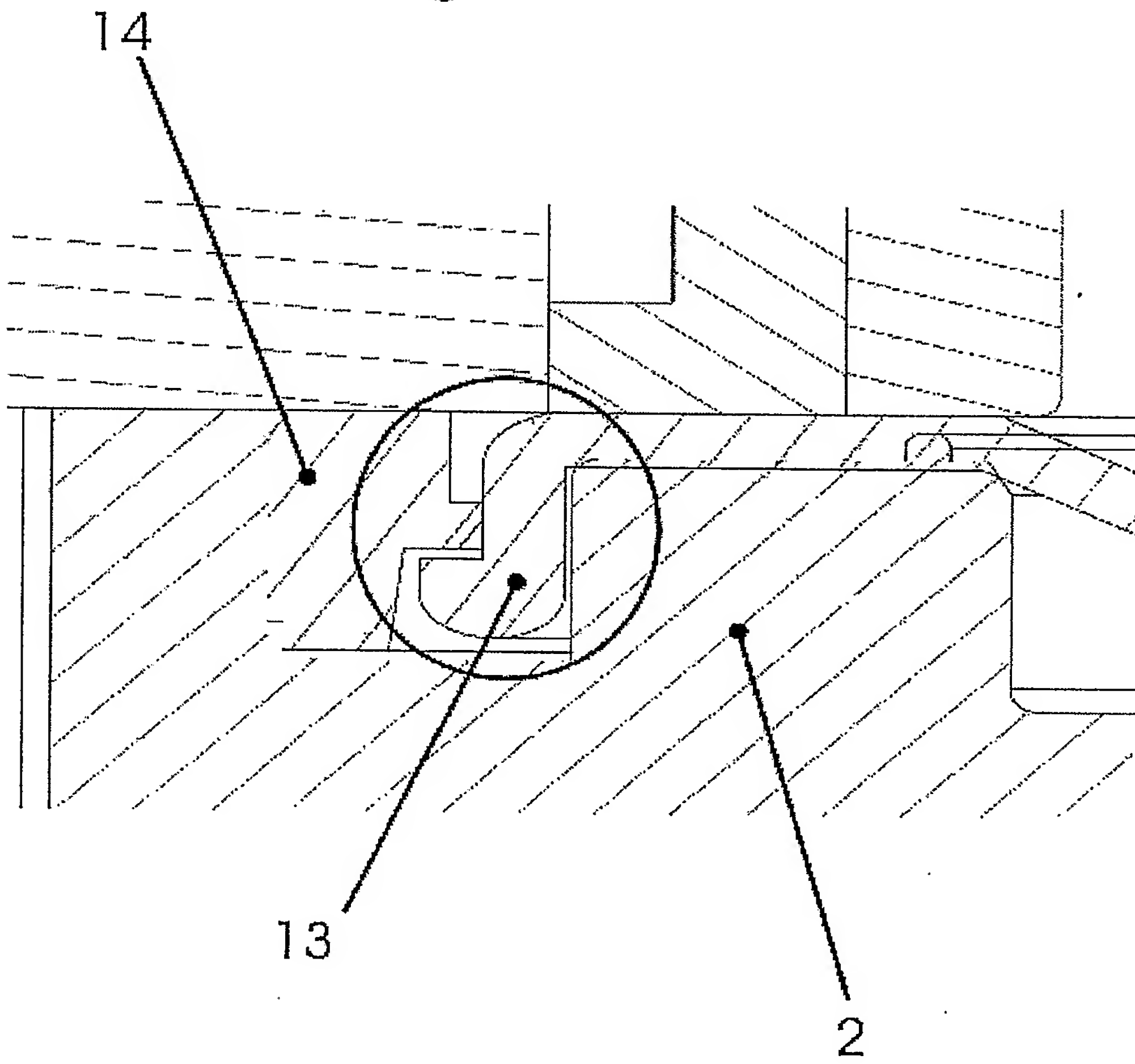


Fig. 14a

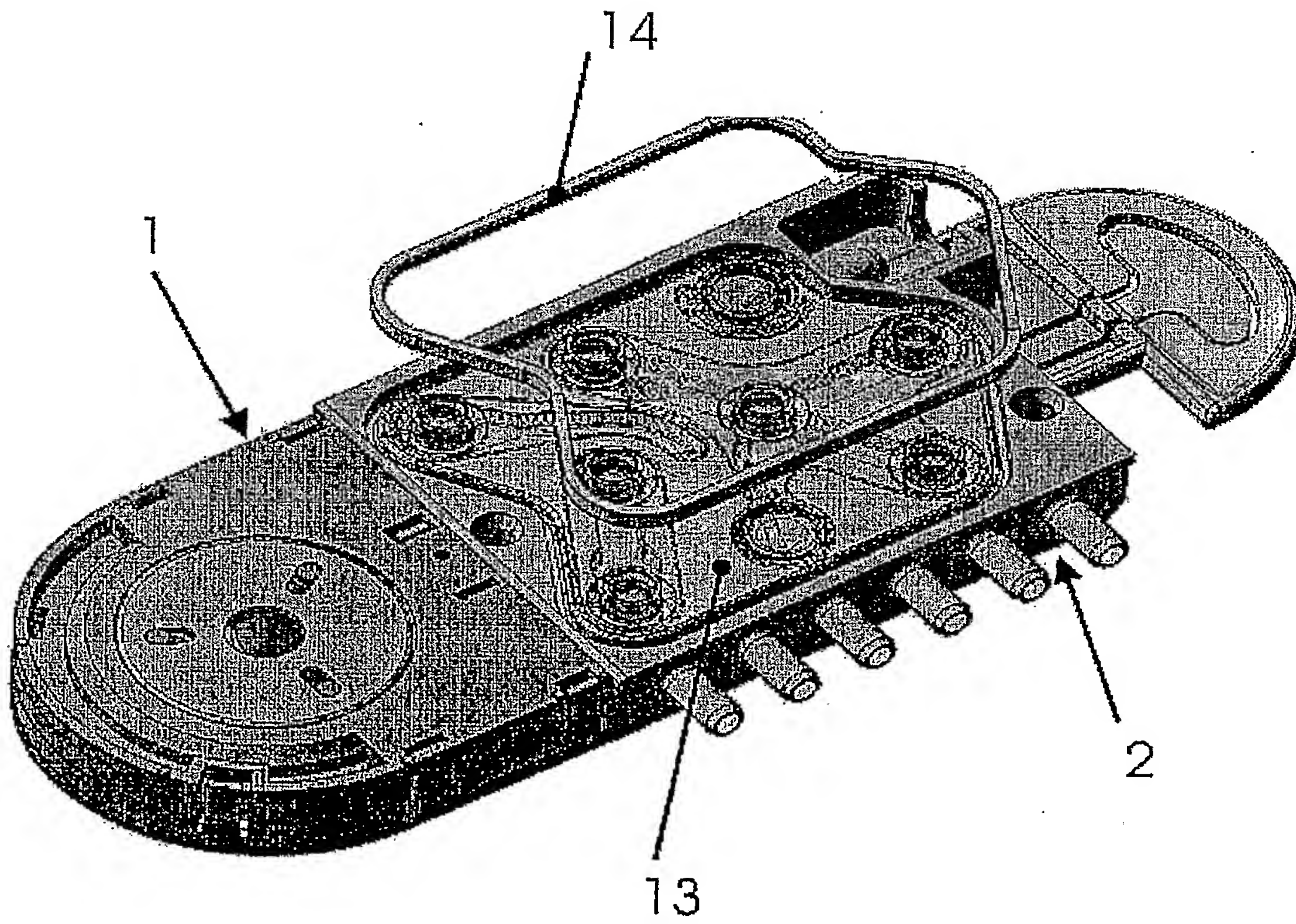


Fig. 15

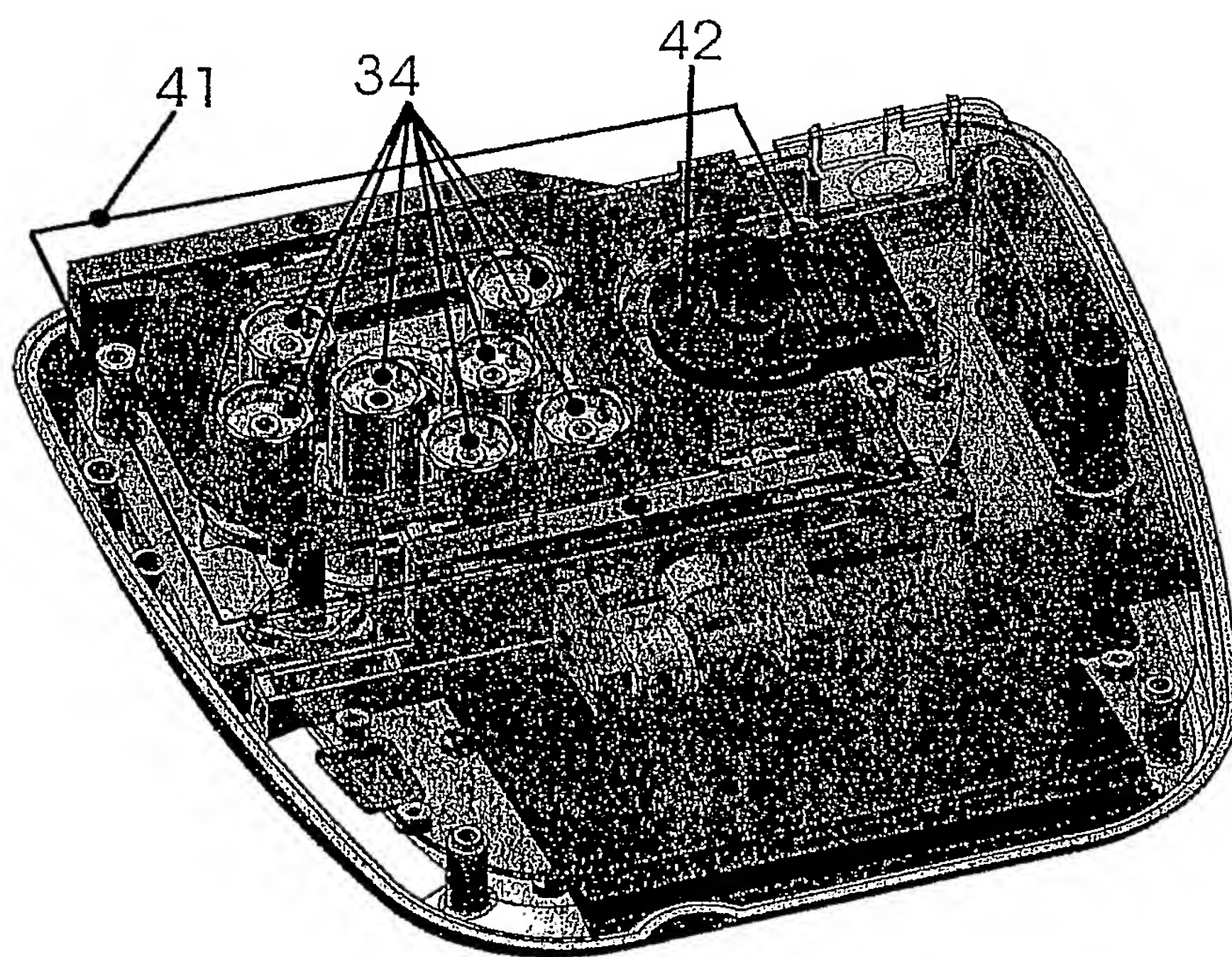


Fig. 16

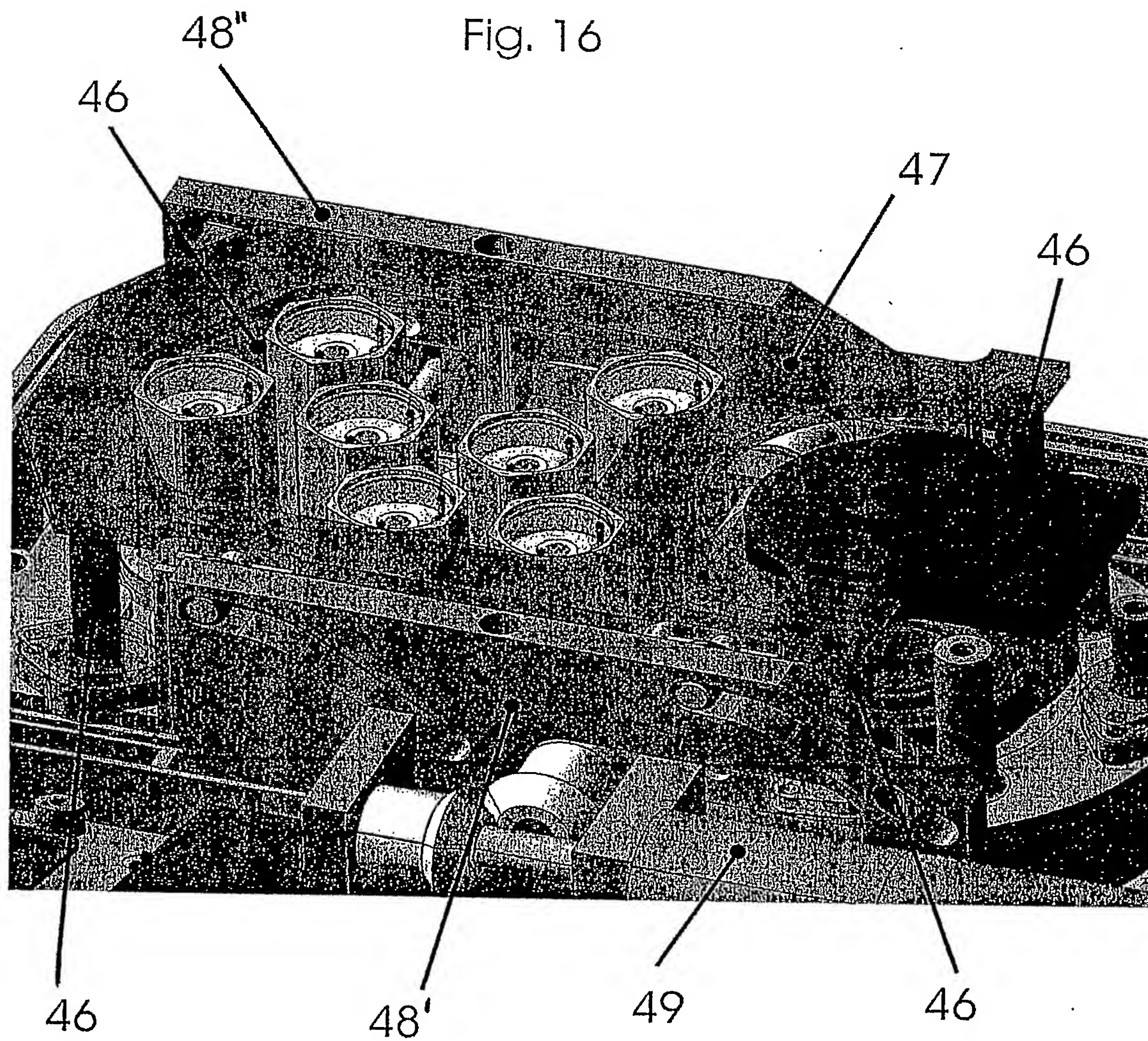


Fig. 17

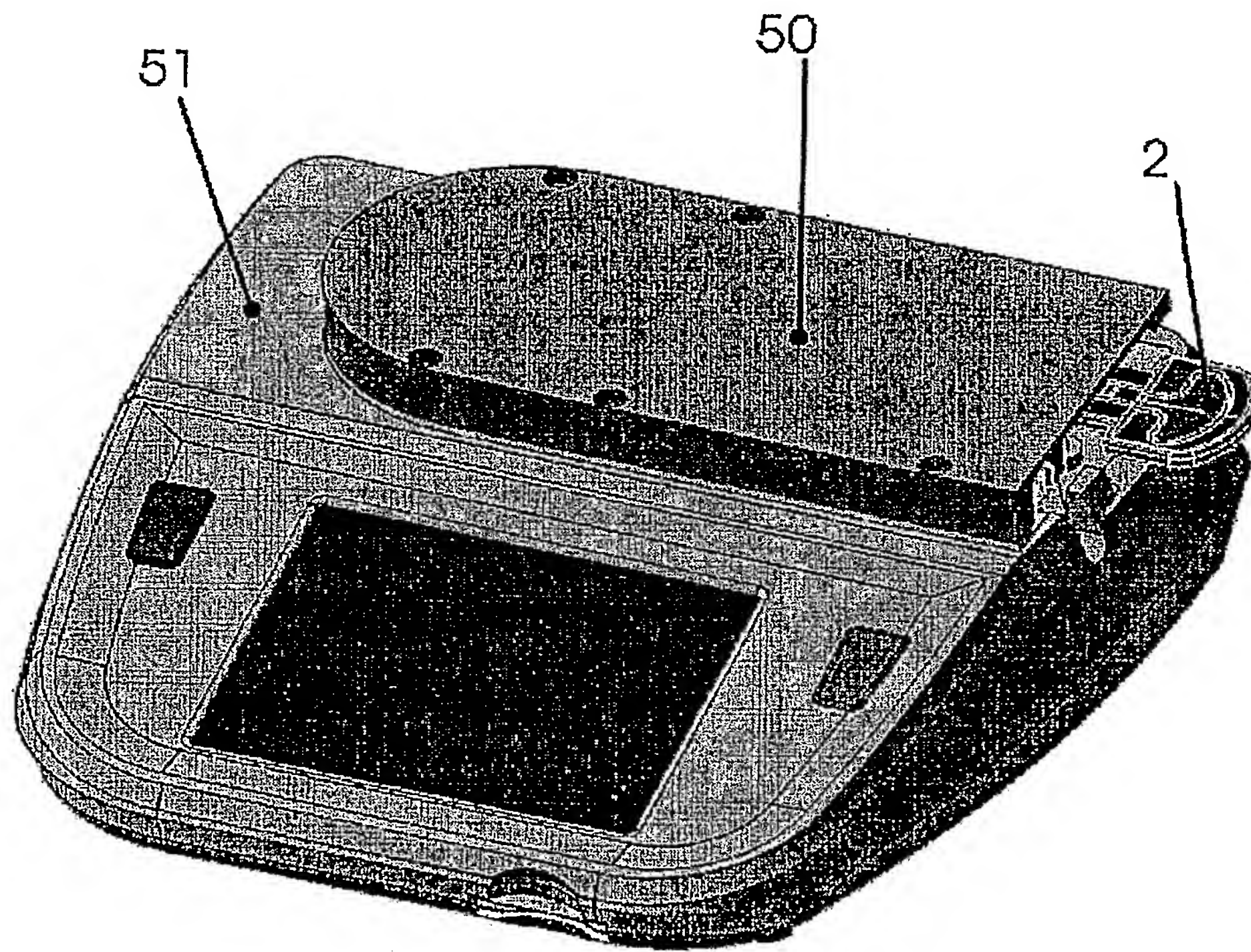


Fig. 18

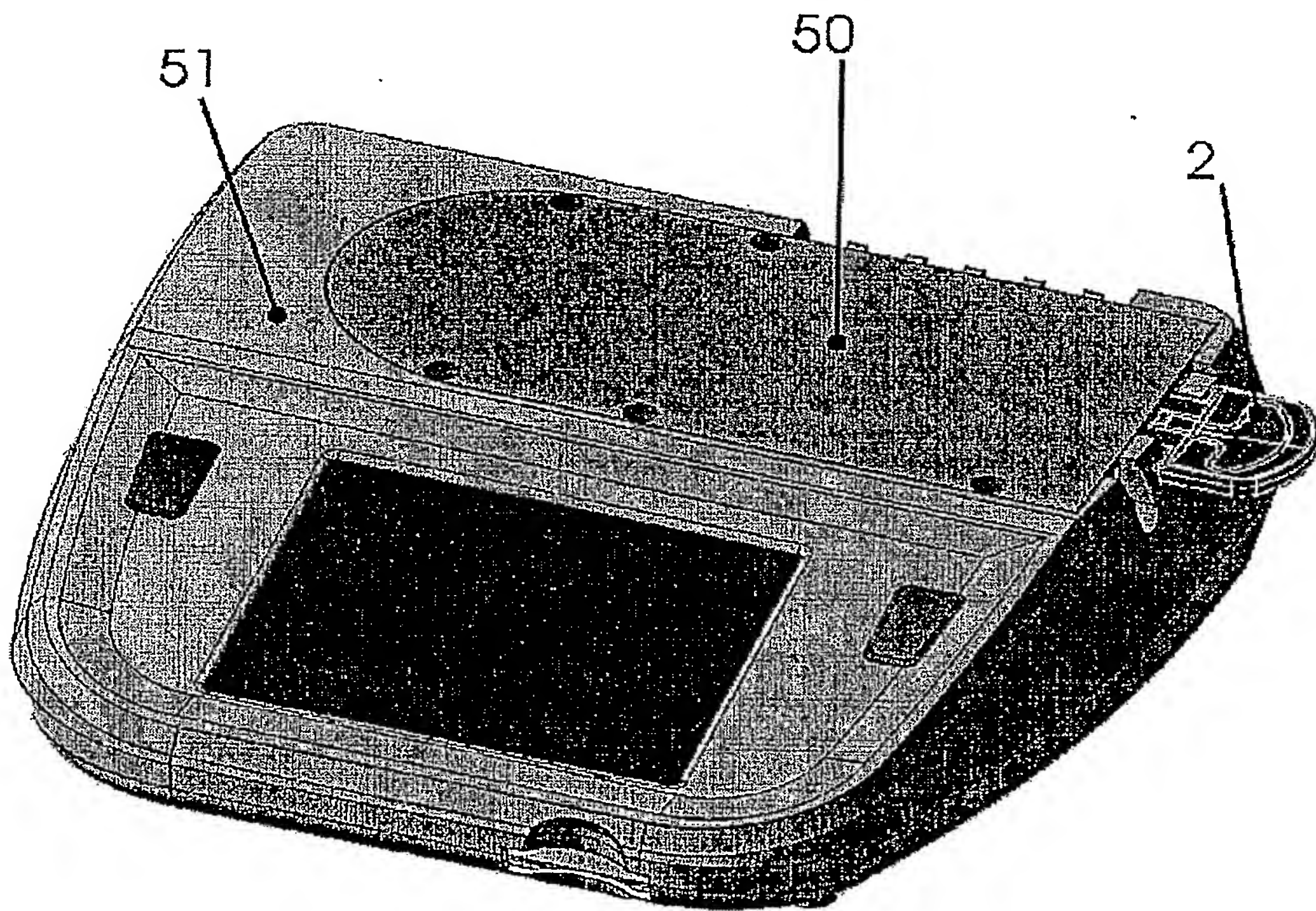


Fig. 19

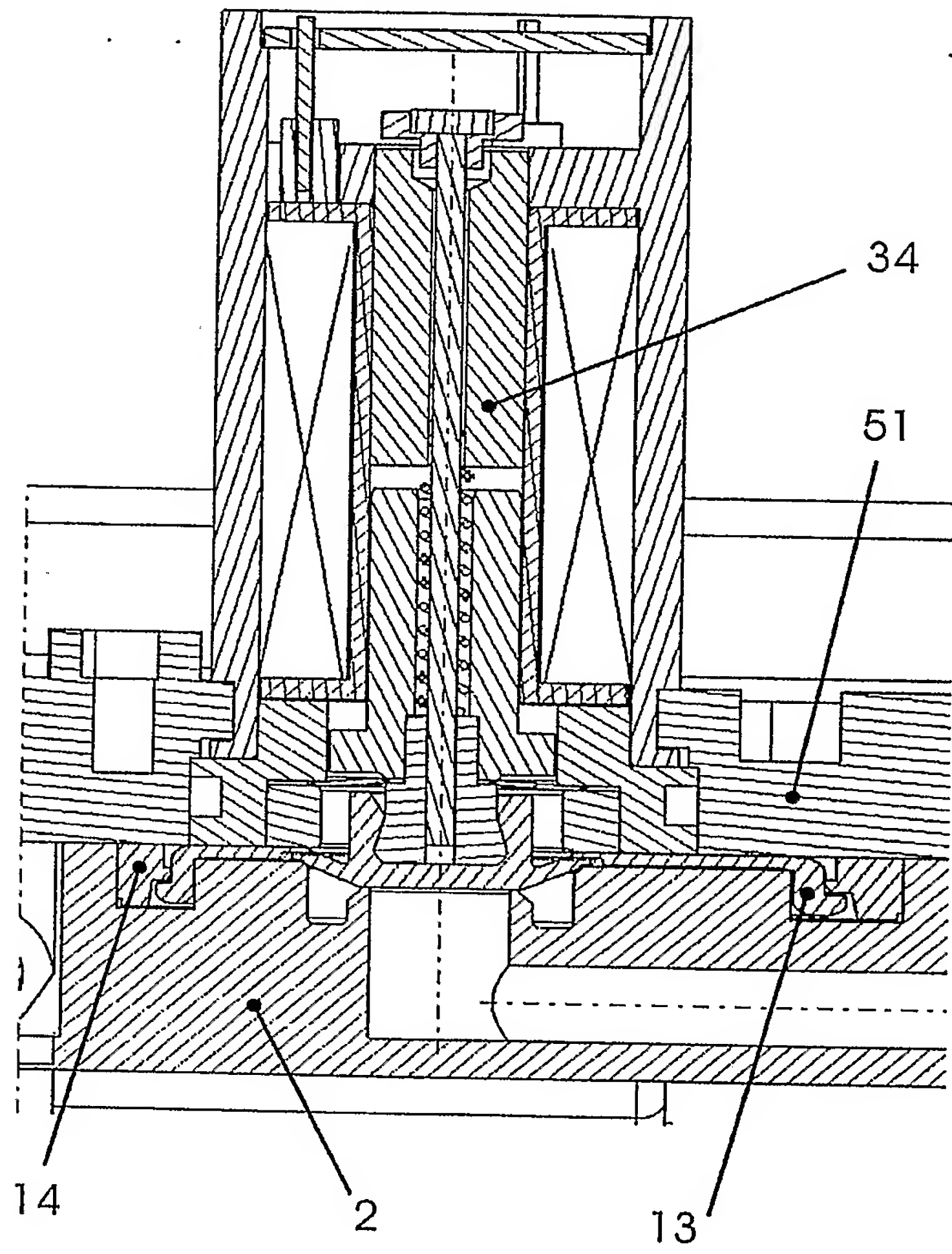


Fig. 20

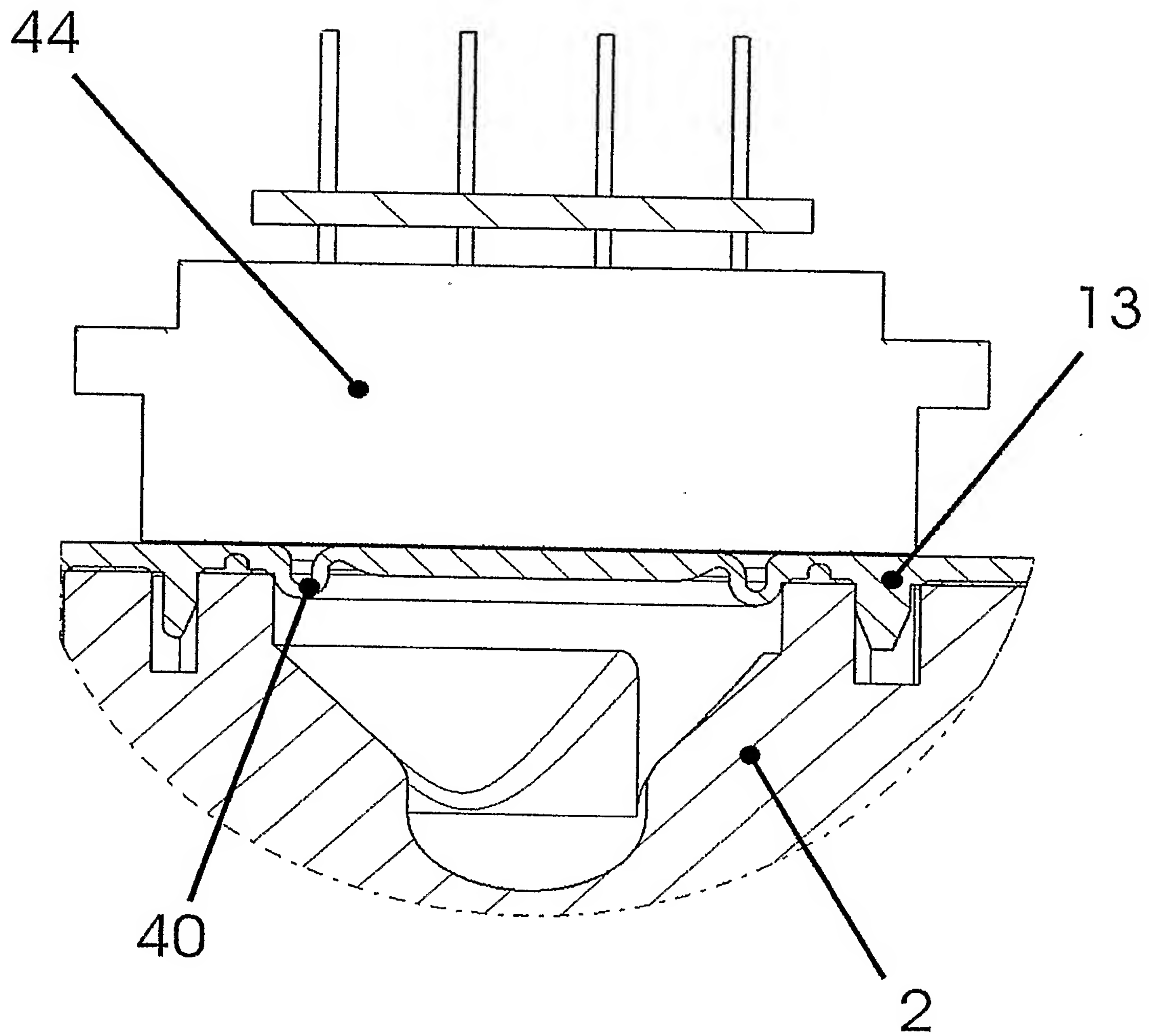


Fig. 21

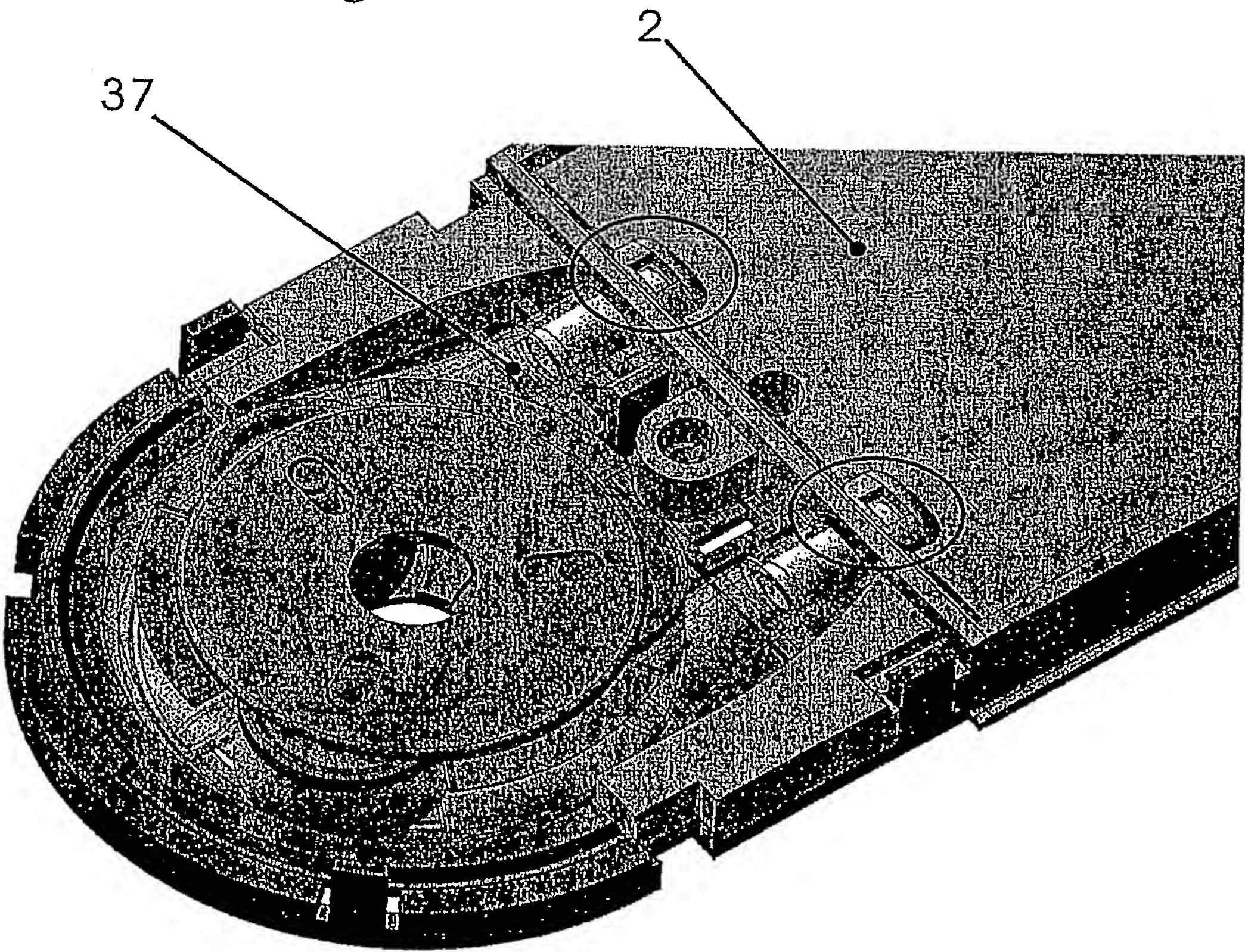


Fig. 22a

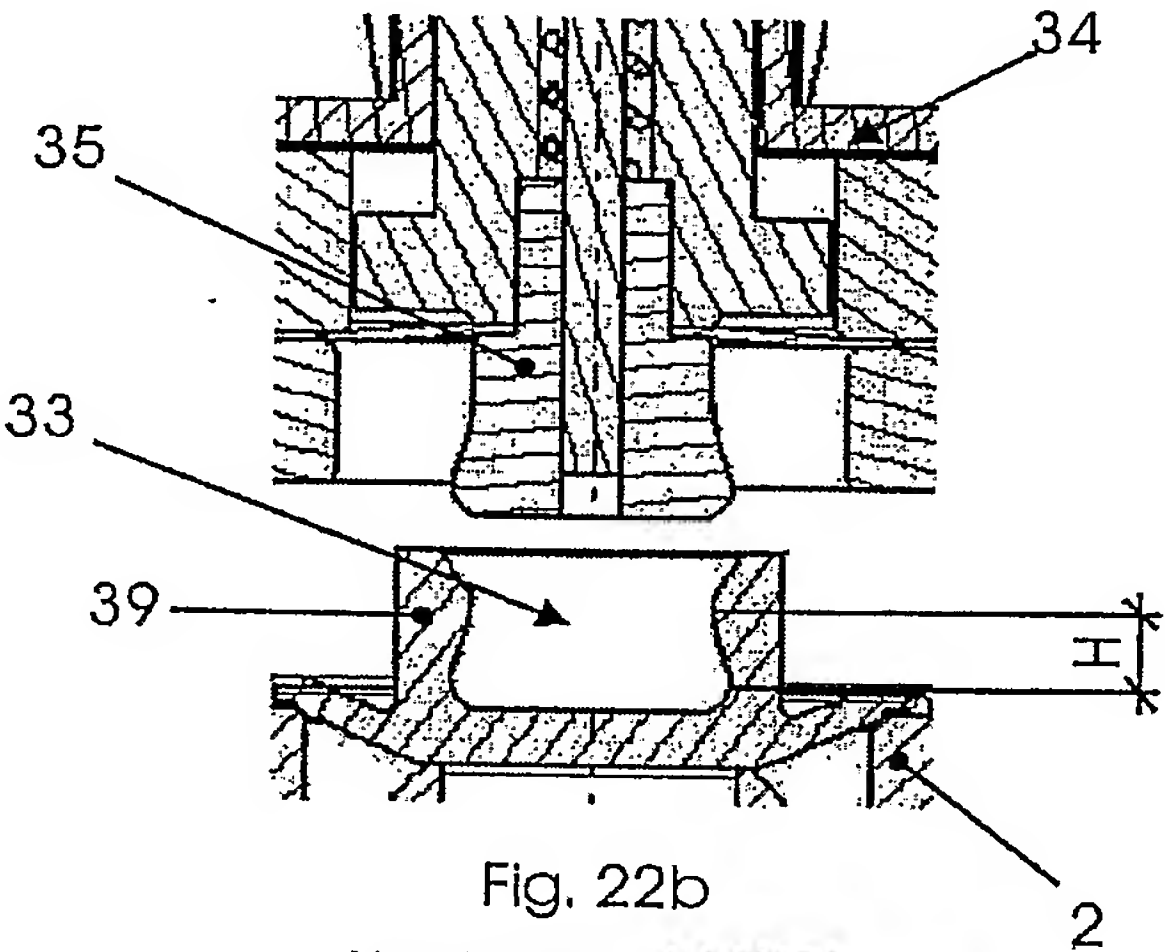


Fig. 22b

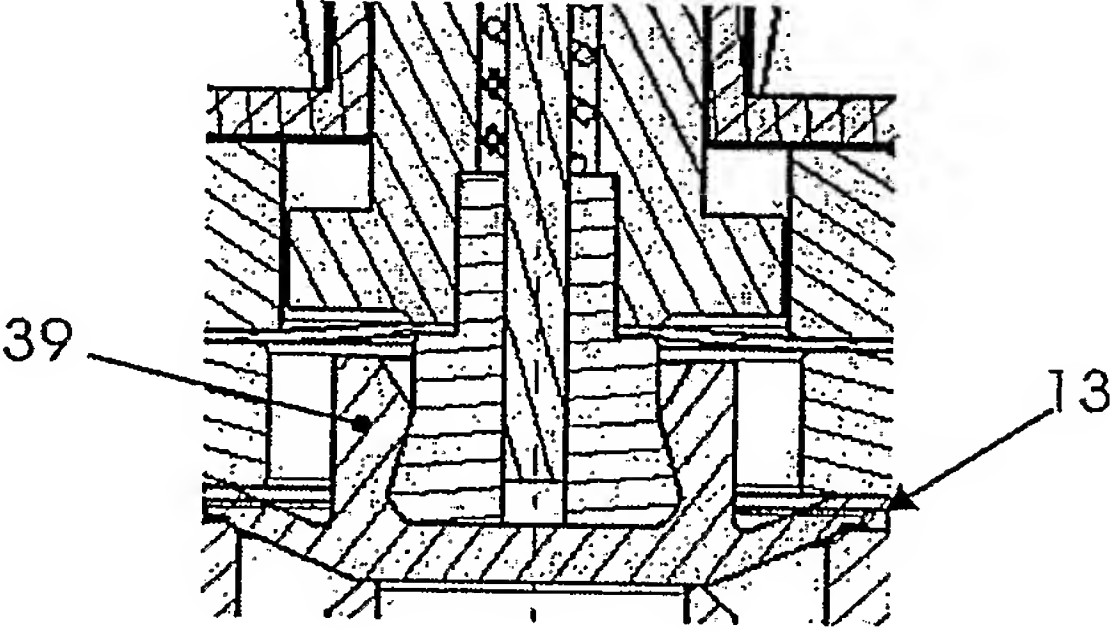


FIG. 23

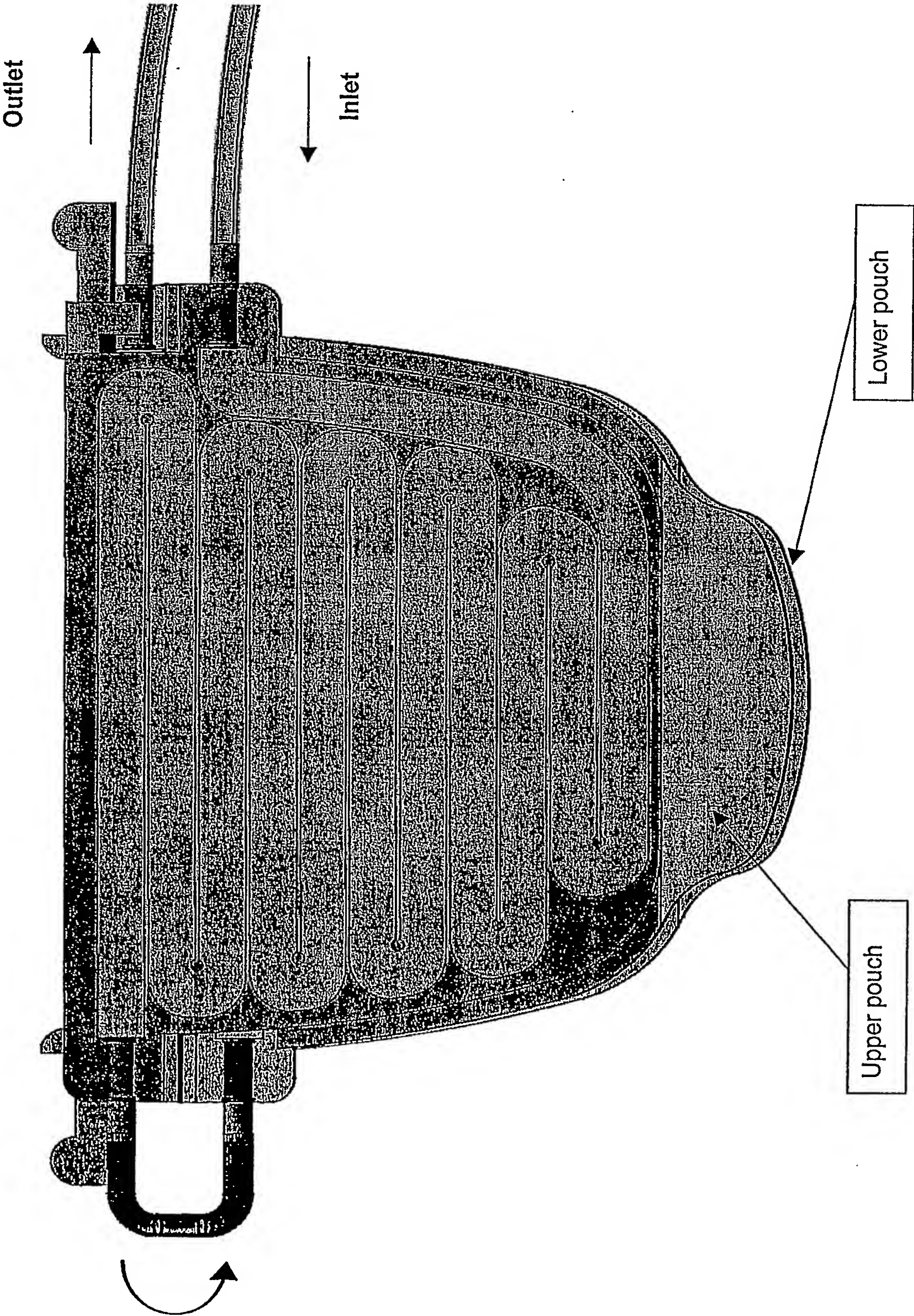


FIG. 24A

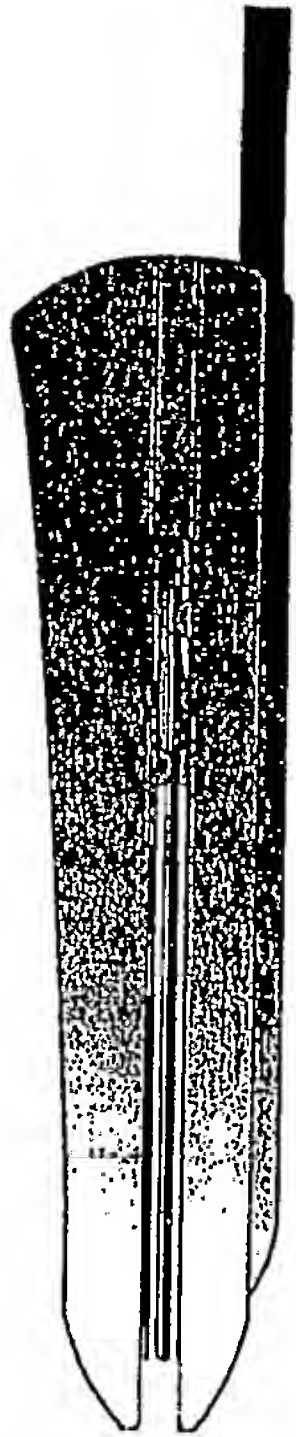


FIG. 24B

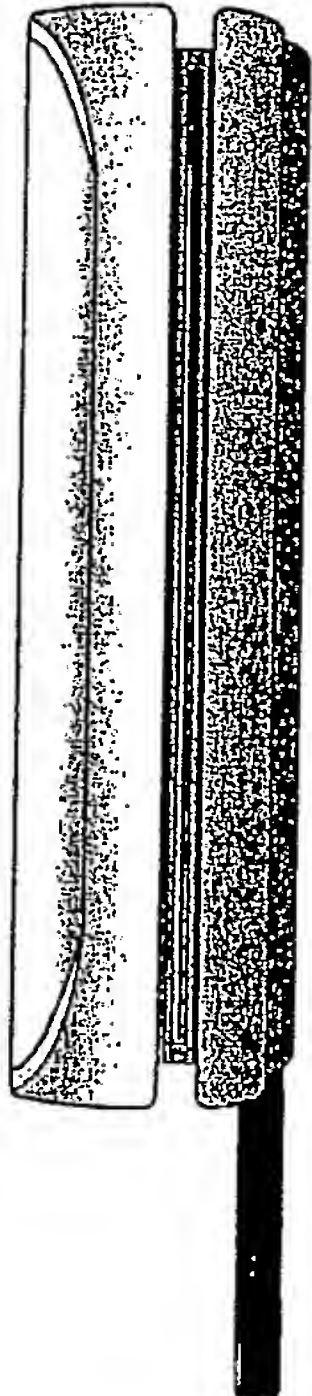


FIG. 24C

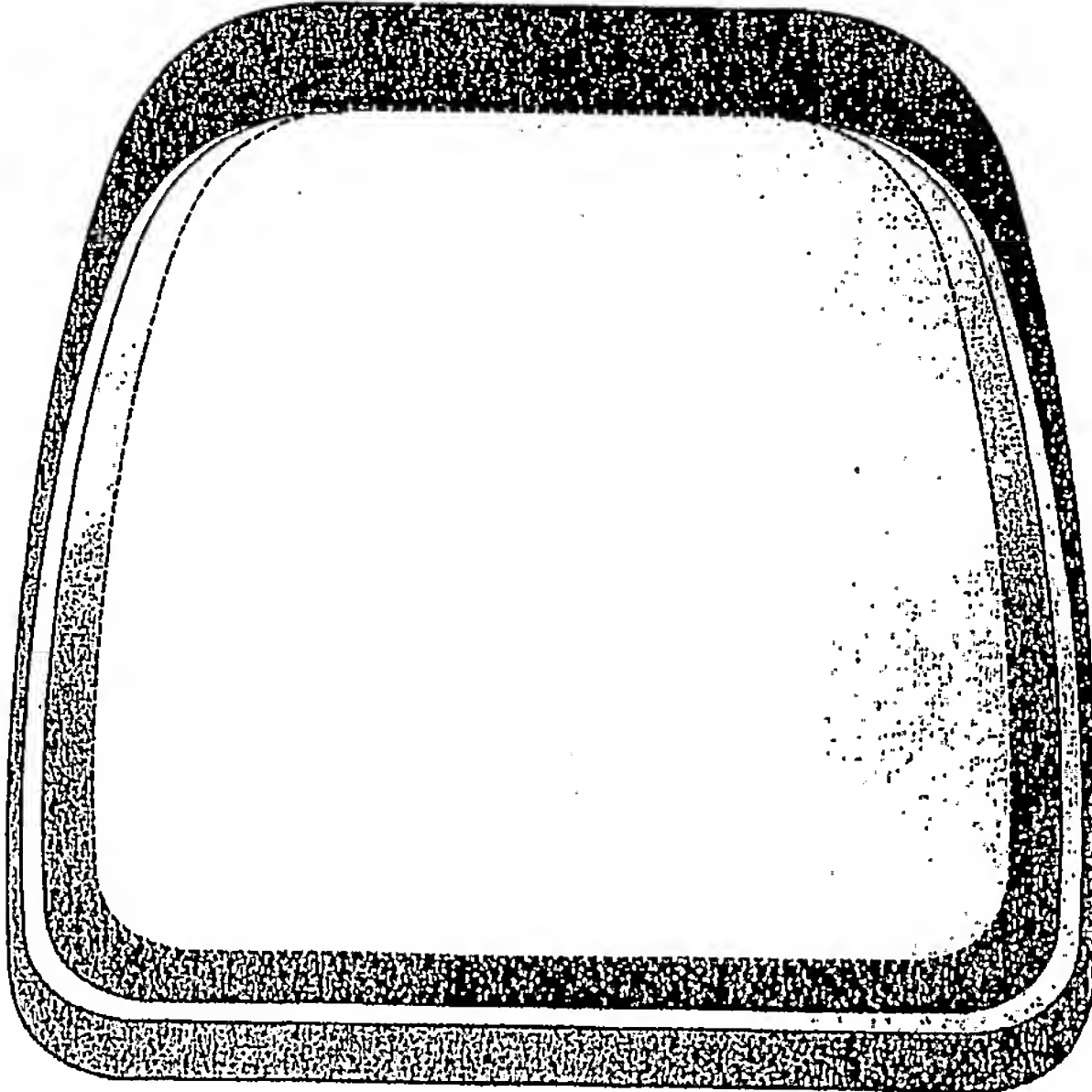


FIG. 25

DRAIN ANALYSIS APD

Cycle 1		Cycle 2		Cycle 3		Cycle 4		Cycle 5		
Vol.	Q [l]/[min]	Vol.	Q [l]/[min]	Vol.	[l]/[min]	Vol.	Q [l]/[min]	Vol.	Q [l]/[min]	
[min]	[ml]	[ml]	[l]/[min]	[ml]	[l]/[min]	[ml]	[l]/[min]	[ml]	[l]/[min]	
0	2330	2752		2503		2665		2736		
1	2131	2600	0.152	2294	0.209	2490	0.175	2580	0.156	
2	1900	2375	0.225	2087	0.207	2253	0.237	2348	0.232	
3	1681	2158	0.217	1860	0.227	2035	0.218	2120	0.228	
4	1453	1941	0.217	1637	0.223	1809	0.226	1892	0.228	
5	1233	1725	0.216	1420	0.217	1585	0.224	1651	0.241	
6	1023	1499	0.226	1193	0.227	1369	0.216	1421	0.230	
7	797	1292	0.207	976	0.217	1143	0.226	1200	0.221	
8	579	1075	0.217	750	0.226	927	0.216	991	0.209	
9	367	848	0.227	532	0.218	721	0.206	784	0.207	
10	173	644	0.204	326	0.206	512	0.209	583	0.201	
11	72	437	0.207	147	0.179	433	0.079	404	0.179	
12	50	232	0.205	72	0.075	374	0.059	302	0.102	
13	29	74	0.158	35	0.037	307	0.067	228	0.074	
14	20	39	0.035	24	0.031	243	0.094	185	0.043	
15	14	25	0.014	20	0.004	169	0.044	172	0.013	
16		17	0.018			121	0.048	125	0.047	
17		10	0.007			79	0.042	87	0.038	
18						46	0.033	80	0.007	
19						26	0.020	64	0.016	
20						5	0.021	52	0.012	
21						0	0.003	27	0.025	
22	Patient BH									
23										
24										

FIG. 26

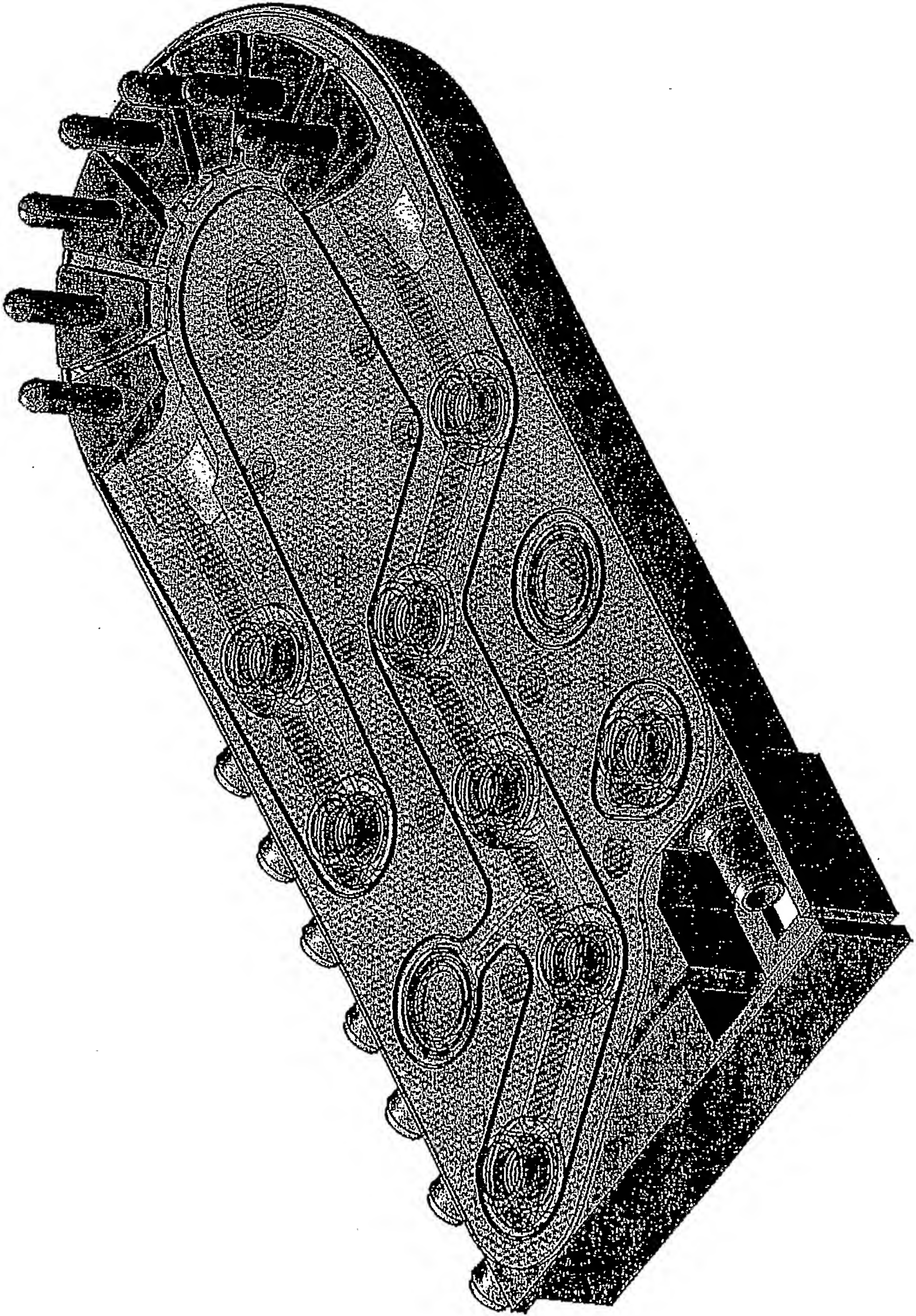
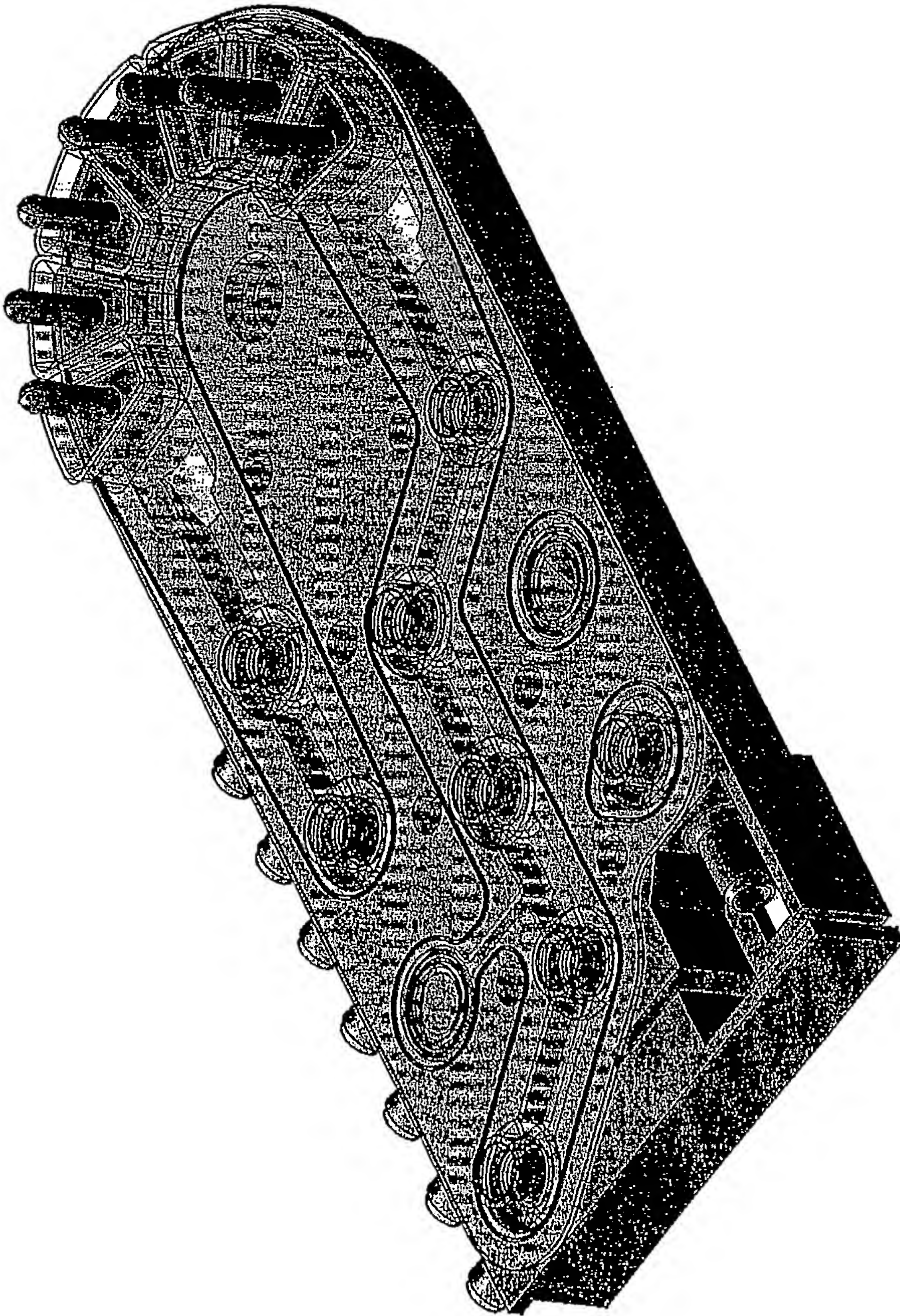


FIG. 27



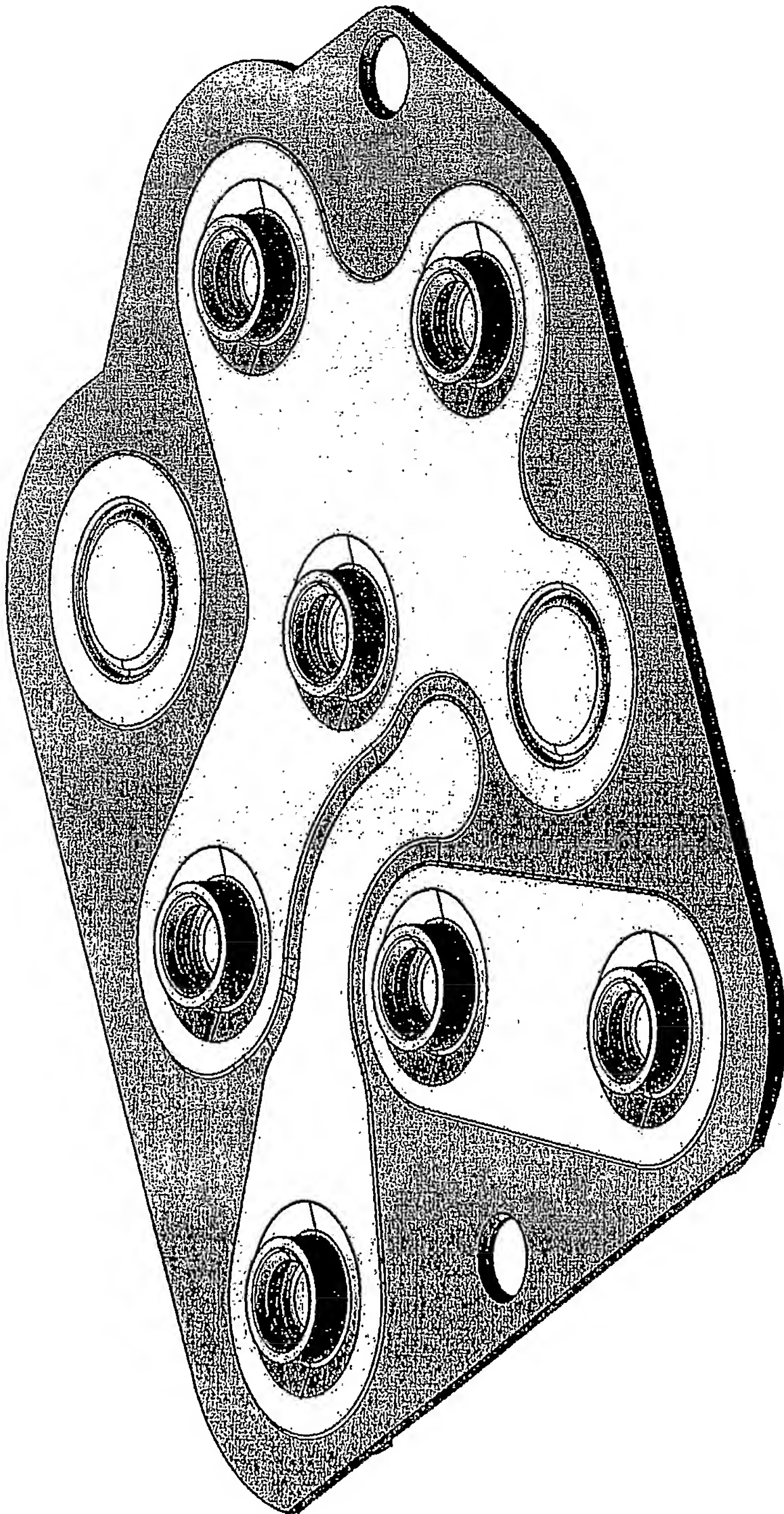


FIG. 28

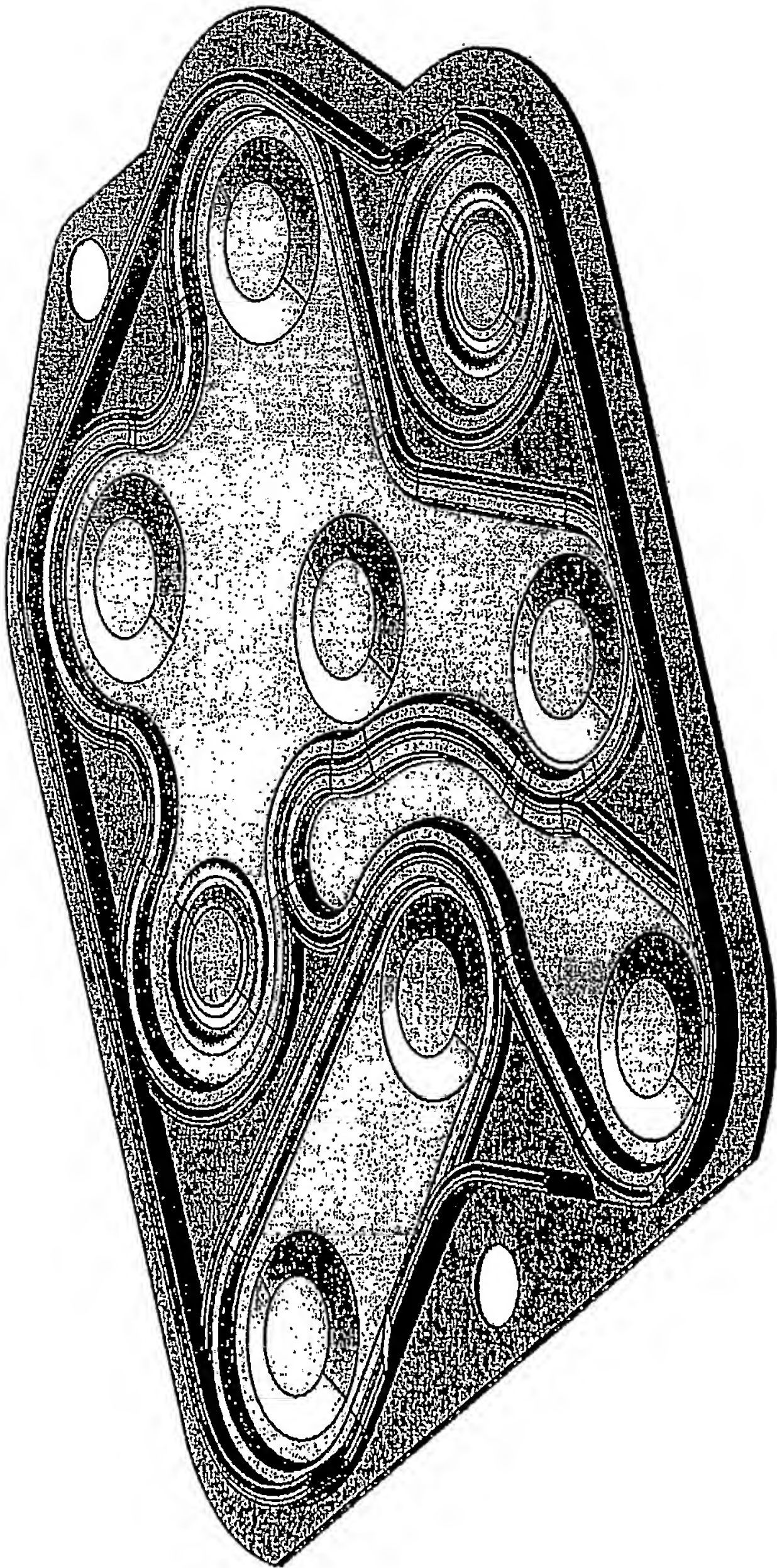


FIG. 29

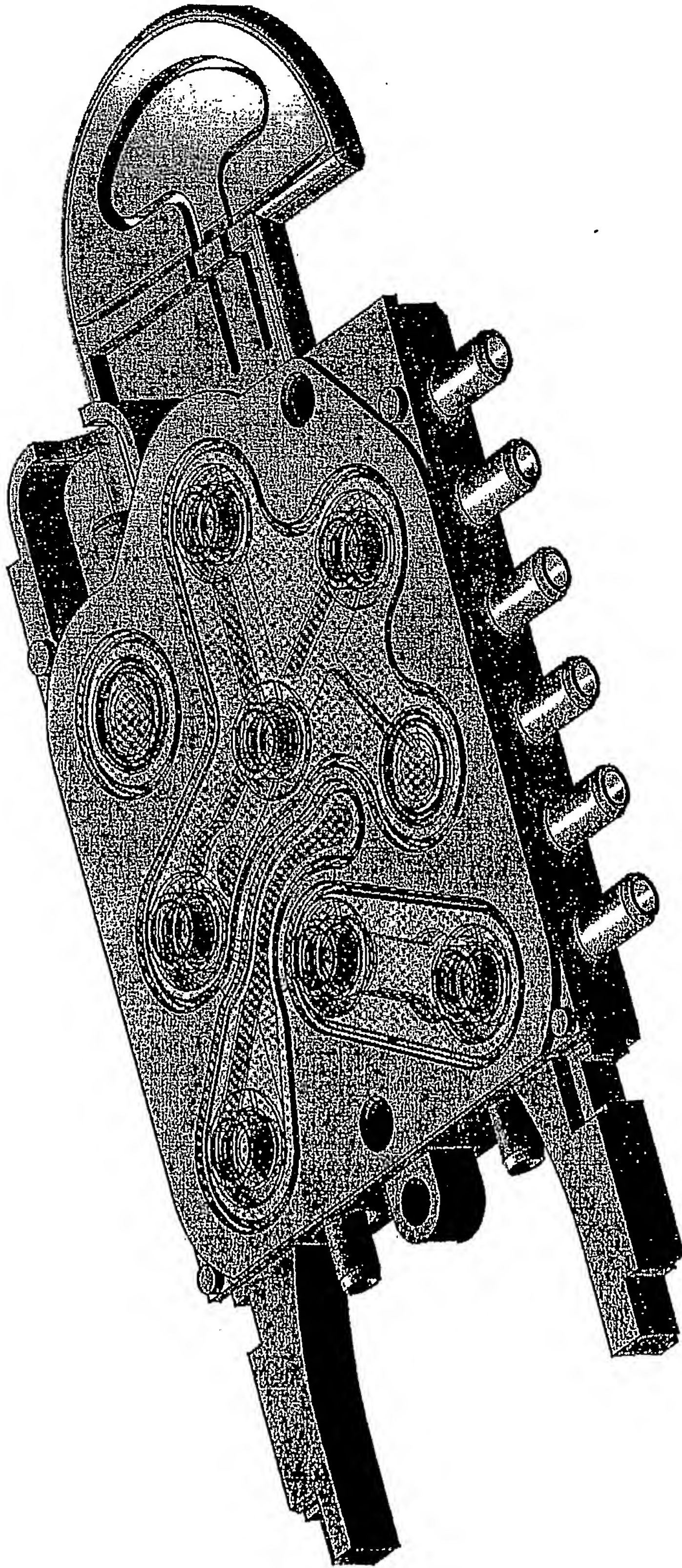


FIG. 30

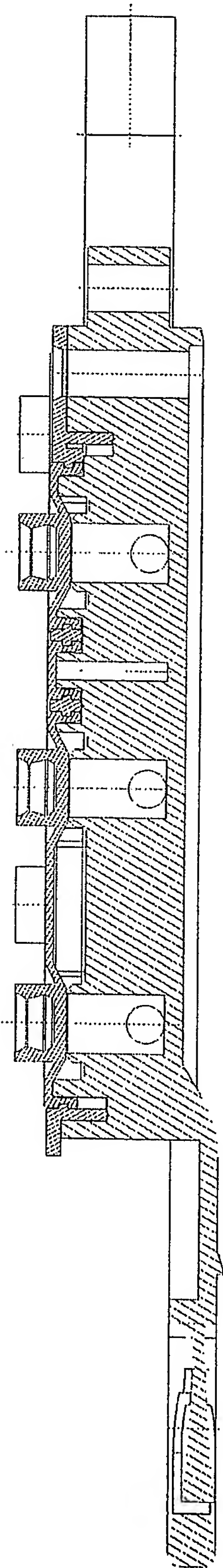


FIG. 31

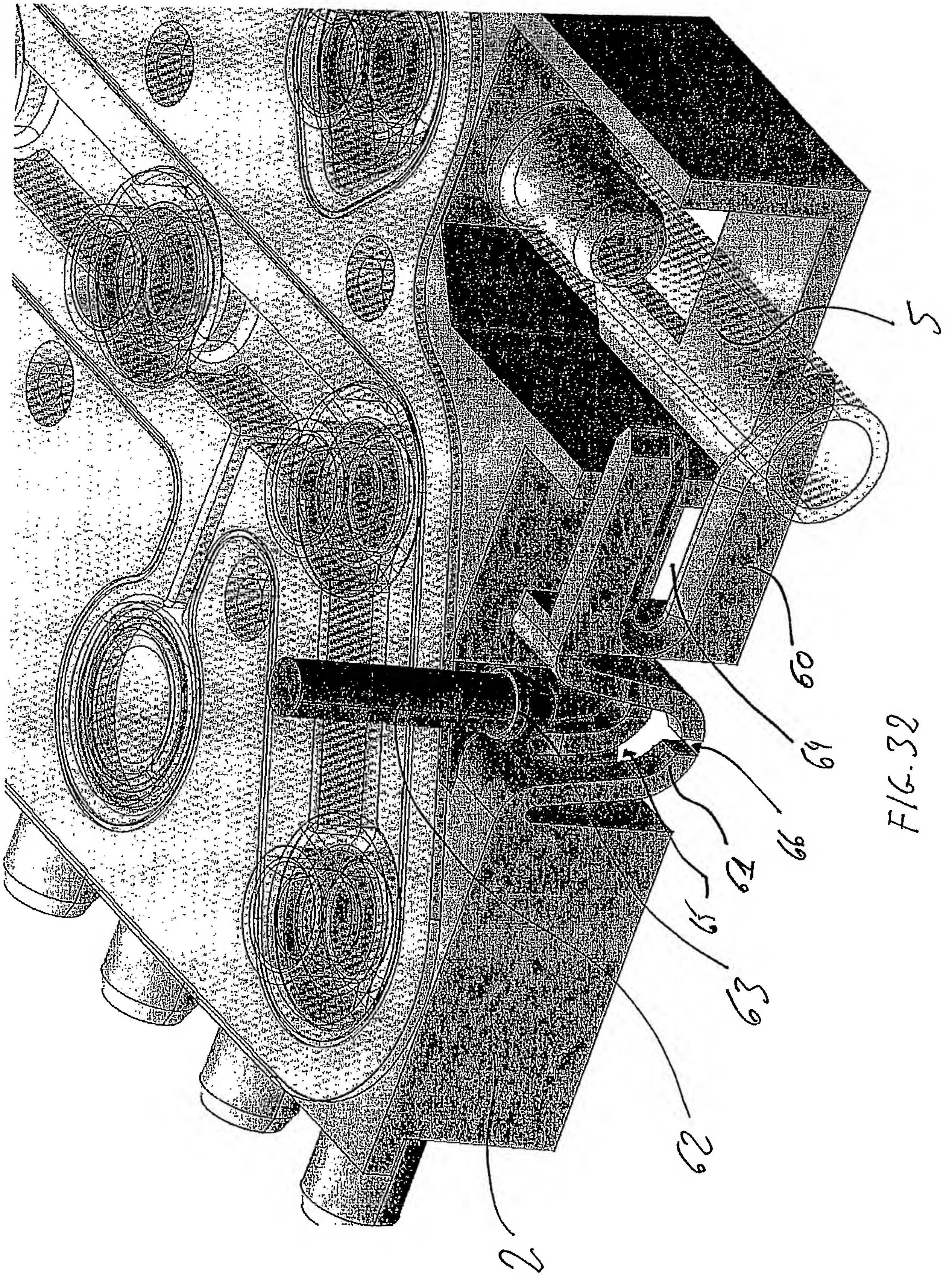


FIG. 32